UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Hon. Patti B. Saris
United States of America, et rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc. No. 07-CV-11618-PBS	)	

ABBOTT LABORATORIES INC.'S RULE 56.1 STATEMENT OF ADDITIONAL FACTS IN OPPOSITION TO VEN-A-CARE'S MOTION FOR PARTIAL SUMMARY JUDGMENT

I. THE LIST PRICES AND WACS FOR THE ERY DRUGS WERE REAL PRICES SET BY ABBOTT PPD FOR LEGITIMATE BUSINESS REASONS, AND ABBOTT MADE SIGNIFICANT SALES AT THOSE PRICES

A. Price Competition From Generic Manufacturers Motivated Abbott PPD To Use Contracts And Terms To Offer Discounts Below The List Prices.

1. Abbott Laboratories Inc. ("Abbott") originally developed, priced, marketed and sold the Ery formulations as brand name drugs. (1/22/09 Pavlik Dep. at 44:22-45:1, Ex. 1.) As branded drugs, the Erys were sold at List Prices and WACs. (30(b)(6) Fiske Dep. at 373:23-374:2, Ex. 2; 1/15/09 Lehn Dep. at 177:2-10; 206:1-14, Ex. 3.)

2. Over time, the Ery formulations lost their patent protection and other manufacturers began selling generic versions at lower prices. (1/15/09 Lehn Dep. at 20:4-11, Ex. 3.)

3. To meet competition from the generic erythromycins and to maintain market share, Abbott began offering lower prices on the Erys, selling them as generic, multi-source drugs. (1/15/09 Lehn Dep. at 19:7-12, Ex. 3.) Abbott began to offer its customers terms and contracts for the Erys, under which customers could obtain discounts and rebates in exchange for meeting certain volumes and share requirements, providing sales data to Abbott, and other considerations.

(Abbott/RiteAid Erythromycin Agreement, Ex. 4; 30(b)(6) Fiske Dep. at 45:17-46:8; 363:2-22, Ex. 2.)

4. Abbott's contract prices were set to allow the Erys to compete with, but not necessarily beat, the prices offered by the competitor generic manufacturers. (12/17/08 Senger Dep. at 16:8-21, Ex. 5.)

5. PPD occasionally raised contract prices for the Erys. (*Id*. at 123:18-125:9.)

B. Abbott PPD Made Substantial Sales Of The Ery Drugs At The List Prices And WACs

6. List Price was a price in Abbott's price catalogs and the price available to customers which did not have a negotiated contract with Abbott and which purchased less than a case of Ery. There were sales at List Price. (2/19/09 Parker Dep. at 75:15-76:5, Ex. 6; 12/17/08 Senger Dep. at 146:2-5, Ex. 5; 1/15/09 Lehn Dep. at 100:14:14-22, Ex. 3 (When stores "ran out of a product and needed to get it before they were reimbursed by their own distribution centers, they purchased at list."); *id*. at 113:6-13, ("not every pharmacy belonged to a retail buying group.); *id*. at 214:23-215:6; Young Aff ¶ 3, Ex. 7.)

7. Customers not on contract and purchasing a case or more of Ery, and until 2003 less than $500 of Ery, paid Wholesale Acquisition Cost ("WAC"). (12/17/08 Senger Dep. at 34:17-21, Ex. 5.) There were sales at WAC. (1/15/09 Lehn Dep. at 215:8-10, Ex. 3; 12/17/08 Senger Dep. at 173:18-174:8, Ex. 5 ("If somebody came to us directly and wanted to buy a case, they would pay us WAC."); Young Aff.¶ 3, Ex. 7.)

8. Until July 2003, customers without an Ery contract which purchased $500 or more of Ery on a single invoice were eligible for Base Deal Price. (*See* Ex. 8 (Garvin Exhibit 10) discussing terms for Base Deal Price); 30(b)(6) Fiske Dep. at 71:8-20, Ex. 2.) John Pavlik, national account manager, described the base deal requirements:

Q. What is base deal price?

A. Base deal price was a price that on our erythromycin line, that wholesalers could buy our product. I believe they had to buy $500 worth of product to get that deal price.

Q. Did you find that wholesalers always met the $500 minimum purchase order?

A. I can't speak for all wholesalers, but I know for some it's a stretch, even the small guys.

Q. Did you find that those, the small guys as you say, the smaller wholesalers, could meet the $500 minimum?

MR. BERLIN: Objection form, foundation.

BY THE WITNESS:

A. Sometimes they couldn't.

BY MR. ANDERSON:

Q. And in those instances, what would happen?

A. They would be charged WAC.

Q. And did you learn of this?

A. I knew that if they didn't buy $500 they were going to be charged WAC, yes.

(1/22/09 Pavlik Dep. at 35:2-36:1, Ex 1.)

9. For several NDCs, the Base Deal Price was the same as WAC. For others, the difference between Base Deal Price and WAC was between 2% and 30%. (Garvin Exhibit 17. Ex. 9.)

10. After Abbott PPD eliminated the Ery Base Deal Price in July 2003, all wholesalers were invoiced at WAC. (30(b)(6) Fiske Dep. at 87:6-11, Ex. 2; 12/17/08 Senger Dep. at 204:18-205:3, Ex. 5.)

11. Sales data show that the sales at List Price and WAC were real and significant. (Young Aff. ¶ 3, Ex. 7.) For example, 17% of direct customers made 100% of their Ery purchases at 97% of WAC or higher. (*Id.*)

C. Abbott PPD Set Prices For The Erys Based On Legitimate Business Reasons And With No Regard For Government Payments

12. Abbott set the Erys' contract prices, List Prices and WACs without regard to government payments under Medicaid (or any other third-party reimbursement spreads.) (1/15/09 Lehn Dep. at 217:18-218:10, Ex. 3; 2/20/09 Gerzel Dep. at 131:17-24, Ex. 10.)

13. List Price and WAC sales provided high profit margins. (1/15/09 Lehn Dep. at 110:17-21, Ex. 3)

14. List Price and WAC served as a starting price point under which various tiers of discounted contract prices were offered. (12/17/08 Senger Dep. at 162:8-14; 180:11-17, Ex. 5 ("WAC price is the starting point for all of our products. It's the publicly available prices and [] within Abbott's it's the price that you start at when evaluating any type of discount or price for the product.").)

15. Abbott also used List Price and WACs on the Erys to encourage customers to enter contracts through which they would get lower prices and provide services to Abbott. (*See* SOAF ¶ 14)

16. During the relevant time period, Abbott increased the List Prices and WACs for the Erys on no more than five occasions – fewer for some Ery formulations. The increases were the result of inflationary increases on all PPD products and to meet perceived competition at list prices. (Young Aff.¶ 4, Ex. 7; 30(b)(6) Fiske Dep. at 47:10-23, Ex. 2.) Young determined that the List Prices for the Erys increased at a significantly slower rate than that of the consumer price index during the same period. (Young Aff. at 4, Ex. 7.)

17. Mr. Fiske described the factors Abbott used in setting the prices for Erythromycin products: "We evaluated a number of things in terms of the pricing of the erythromycins, we evaluated the competitive circumstances in the marketplace, we evaluated our own market share for the products and determined if we felt we could take price actions. (30(b)(6) Fiske Dep. at 41:8-12, Ex. 2.)

> Q. Prior to July of 2003 for the erythromycin products, how were the WAC prices that were published by Abbott to the compendia such as First DataBank and Red Book set?
>
> A. I -- I think I testified to this already today. I think that I explained that we evaluate competitive circumstances in the marketplace. It's no different for WAC pricing than it is for contract pricing, because, remember, we always have customers that are purchasing at WAC and list price and we want to maximize our margins. We evaluated the -- we evaluate the competitive situation, what kind of market share do we have for our products, what has inflation been over time. In -- in this case, we al- -- we also look at the WAC pricing for our competitors. It's hard to discern contract pricing for competitors. That information is not readily available. But after we have done that, we determine if there's an opportunity to take a price increase. I told you that we took a total of five price increases from 1994 to present.

(*Id*. at 80:2-24.)

18. Abbott did not market any price spreads on the Ery drugs. Abbott witnesses denied doing so. For example Mr. Fiske, Russ Lehn and Ms. Parker testified as follows:

Mr. Fiske, Director of Pricing and Planning for Abbott PPD:

> Q. (BY MR. ANDERSON): Did Abbott provide spreads by reporting high inflated estimated AWPs or AWPs to the pricing compendia?
>
> MR. BERLIN: Objection, form.
>
> A. No.
>
> Q. (BY MR. ANDERSON): With respect to the erythromycins that were selling for much less than the AWPs, will you agree that

Abbott was enabling chains to achieve more reimbursement spread on those drugs?

MR. BERLIN: I'm sorry. Could I have the question back?

(Requested testimony read back.)

MR. BERLIN: Objection, form.

A. No.

Q. (BY MR. ANDERSON): Why not?

MR. BERLIN: Objection, form.

A. Numerous reasons. As I've indicated, we reported the WAC and the list price that we were actually selling product for in the marketplace. Some of those purchasers were, in fact, retailers. In addition, the actual reimbursement for the products in question were not a- -- not always even based on AWPs. There are, as we discussed previously, numerous formulas for determining what a maximum allowable cost will be for a product, and some of those have no relationship to AWP whatsoever. So the answer is "no".

(30(b)(6) Fiske Dep. at 304:5-305:7, Ex. 2.)

***

Mr. Lehn, Manager of Pricing and National Accounts for PPD:

Q. Based on your experience, what factors did Abbott consider when setting prices for the erythromycin drugs?

A. Competition, having a full line of product, quality of the product, dependable distribution, reliable distribution, distribution cost, cost of the product.

Q. Did you ever observe anyone at Abbott consider the reimbursement spread when setting prices for erythromycin?

A. No.

Q. Did you ever observe that Abbott increased the list price, or the WAC, for any of the erythromycin drugs in order to increase the reimbursement spread?

A. No.

Q. To your knowledge, was that ever a consideration in price setting at Abbott?

A. Not to my knowledge.

Q. And I asked you about factors considered for setting price. What factors about Ery did Abbott market to its customers in the 1993 through '96 period?

A. Those that I mentioned earlier, other than the cost of the product.

Q. To your knowledge, did any Abbott employee market the spread between erythromycin's cost to the provider and the reimbursement amount?

A. Not to my knowledge.

Q. And did you ever learn that wholesalers were marketing the spread on the erythromycins? Did you have any specific knowledge of that?

A. No.

(1/15/09 Lehn Dep. at 217:18-218:23, Ex. 3.)

***

Ms. Parker, Director of Trade Relations:

Q. (BY MR. ANDERSON): Have you ever heard AWP spread referred to as a potential talking point with customers?

A. No.

Q. Would that type of activity be condoned by Abbott?

A. No, it would not.

Q. Why not?

A. It's not our business how they profit. We have to sell our product based on the merits of our product, which have to do with its clinical effectiveness, its availability, its, you know, reliability, and that's the methods that we use to sell our products.

(2/19/09 Parker Dep. at 97:23-98:11, Ex. 6.)

(a) Abbott's marketing expert, Dr. Brian Reisetter opined if Abbott implemented a broad strategy to market the spread on Ery he would have expected to find evidence of the following indicators:

(1) Consistent documentation as to how best market the message of provider profitability.

(2) Continuous process of building a product strategy and core message around the topic of marketing the spread.

(3) Consistent and continuous research on the issue of provider profitability as a potential driver of sales.

(4) Extensive and explicit research on the correct messages and materials to be used by representatives to market the spread.

(5) Evidence of continuous competitive intelligence research in the area of competitor pricing and "spread."

(6) Continuous internal training on how providers are compensated as a basis for making decisions on marketing the spread, including specific training on provider compensation by payer type and geographical region.

(7) On-going and explicit development of training materials needed for marketing the spread. (Reisetter Expert Report at 39, Ex. 11.)

(b) Ven-A-Care's marketing expert Dr. Perri conceded that the record did not contain evidence of any of these indicators. (Perri Dep. at 129:8-9; 147:10-16 ("I did not come across any document in researching or in the depositions or exhibits to the depositions that delineated marketing goals or objectives and that would include marketing spread."), Ex. 12; *id*. at 147:10-148:2 (no internal discussion about a specific plan to market the spread on Ery.); *id*. at 155:12-16) (no evidence of documents explicitly discussing the goal of maximizing provider reimbursements that were disseminated repeatedly over time); *id*. at 151:13-152:21 (No evidence of internal discussion regarding how best to market the message of provider profitability); *id*. at 153:22-153:3 (no evidence of research on the correct message and materials to be used by representatives to promote the spread.) *id*. at 155:4-11 (no evidence of competitive intelligence

or research on Abbott's competitors pricing in their spread); *id*. at 40:1-7 (no evidence of a concerted effort by PPD to track the contract prices of their competitors); *id*. at 155:17-20 (no training materials to inform sales representatives how to present the strategy of marketing the spread to customers); *id*. at 153:22-153:3 (no evidence of research on the correct message and materials to be used by representatives to promote the spread.).)

19. To the extent that wholesalers or retail buying groups did disseminate any AWP or spread information on the Erys, Abbott PPD was not aware of wholesalers or retail buying groups disseminating any AWP or spread information on the Erys, and Abbott did not authorize such action. (1/15/09 Lehn Dep. at 163:3-6; 175:25-176:2, Ex. 3.) Chris Pavlik, testified as follows about this:

> Q. Looking at this particular example of a First Facts Notification, you see that it's got AWP pricing included?
>
> A. Yes.
>
> Q. Did you understand that as recently as, for instance, 2002 Cardinal was sending out AWP information to pharmacies?
>
> A. No.
>
> Q. You knew they were notifying pharmacies about launches but you didn't realize the detailed information they were providing?
>
> A. Not for anything that I participated in, no.
>
> Q. Did you know that Cardinal was communicating AWP information to pharmacies in any way?
>
> A. No.

(1/22/09 Pavlik Dep. at 104:5-21, Ex. 1.)

> Q. Did you become aware in any way that Cardinal was providing AWP information to pharmacies?
>
> A. No.

Q. Did you become aware that Cardinal was calculating spreads for pharmacies?

A. No.

(*Id*. at 107:2-8.)

D. The Abbott PPD Personnel Responsible for Setting and Reporting Prices Were Informed and Understood That Abbott Was Supposed to Report List Prices and WACs To The Compendia

20. On May 26, 1995, Red Book sent a letter to pharmaceutical manufacturers, including Abbott, requesting them to "send [] WAC pricing." (IMNX 012263, Ex. 13.) Red Book defined WAC as "the manufacturer's quoted list price to wholesale distributors and does not reflect any deal terms or specialized contract pricing." (*Id*.) Red Book's Rule 30(b)(6) representative, Kristin Minne, defined WAC as a price that "does not reflect rebates and contract pricing and, you know, discounts for early payment, [etc.]." (11/19/08 Minne Dep. at 396:9-19, Ex. 14.)

21. The U.S. Congress defined WAC for the first time in the Medicare Modernization Act of 2003: "The term 'wholesale acquisition cost' means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price . . ." (42 U.S.C. § 1395w-3a(c)(6)(B), Ex. 15.)

22. Several other sources defined WAC as an undiscounted list price. (*See e.g.* September 2001 GAO Report "Medicare, Payments for Covered Outpatient Drugs Exceed Providers Cost," Ex. 16 (defining WAC as "the list price a wholesaler pays to a manufacturer, but it does not include discounts that may affect the net price").)

23. Several sources defined List Price as an undiscounted price.

(a) List Price is defined by Merriam-Webster's Dictionary as "a basic price of an item as published in a catalog, price list, or advertisement before any discounts are taken." (Merriam-Webster's online dictionary at http://www.merriam-webster.com/dictionary/list%20price (last visited on July 25, 2009).)

(b) In the industry and in common usage, List Price is understood to mean an advertised price not including any discounts. (7/13/07 Scully Dep. at 770:9-15 ("I would assume that a list price does not include discounts."), Ex. 17.)

24. Abbott PPD reported a product's List Price (usually labeled "List Price") and WAC to the pricing compendia at the product's launch and whenever the prices changed. (2/19/09 Parker Dep. at 55:20-56:7, Ex. 6; 30(b)(6) Fiske Dep. at 158:5-16, Ex. 2; Garvin Ex. 16, Ex. 18.)

25. Pursuant to 42 U.S.C. § 1396r-8(k)(1), Abbott reported its Average Manufacturer Prices ("AMPs") quarterly throughout the relevant claims period. AMP is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts. 42 U.S.C. § 1396r-8. Abbott's sales at its contract prices were reflected in its AMPs. (30(b)(6) Fiske Dep. at 188:3-189:11, Ex. 2; 12/17/08 Senger Dep. at 117:3-8, Ex. 5.)

26. According to Ven-A-Care's expert, Dr. Marmor, the numbers reported by Abbott as its AMPs would have satisfied his definition of AWP.

> Q. If what manufacturers reported as their AWP was the AMP or met the AMP definition, would that be sufficient in your view?
>
> MS. THOMAS: Objection. Form.
>
> A. Sufficient for what?
>
> Q. Well, in other words --

A. Just only my simple question is sufficient for what purpose? If you meant by that one purpose would be to lower the estimated acquisition cost the answer would be yes.

Q. Would it have met the standard that the government was setting in your view in the reports it issued that you say the manufacturers should have been aware of?

MR. GOBENA: Objection to form.

A. It certainly would have been a candidate for satisfying that condition because it would have been closer to the actual acquisition costs and closer to then the estimated acquisition cost.

(2/13/09 Marmor Dep. at 873:14-874:11, Ex. 19.) Dr. Marmor also conceded that the government never informed or requested manufacturers to report AWP.

Q. So this is the specification of the AMP policy and it tells the manufacturers what they're supposed to do in an authoritative way?

MR. GOBENA: Objection to the form.

Q. Correct?

A. In a clear way is the way I would put it and in a way that's official and formal.

Q. Okay. Now, in your review of the record and in preparing your report did you find a directive like this definition of AMP that called for drug manufacturers to report any other type of price?

A. Let's go through that once again. Did I -- let me just see if I can understand. You tell me whether I understand the question.

Q. Sure.

A. Did I find in other areas of pharmaceutical agreements and statements of policy as detailed and clear a statement of what the government was expecting, is that your question?

Q. Yes.

A. This is certainly at the end, at the end of the distribution of more extensive and clearer.

Q. Okay. But did you find anything else that was on par with this?

MR. GOBENA: Objection to form.

A. I didn't ask that question so I don't know off the top of my head that I -- I think I feel more comfortable just saying that I know what the other standards were and they were more flexible than this. This is more specified in detail.

Q. Well, what are the other standards that you're referring to?

A. Ones like estimated acquisition cost. Taking into account questions about what -- whether or not this ought to be net of discounts.

Q. You mean estimated acquisition costs?

A. Whether estimated acquisition costs should be net of discounts that your estimation process.

Q. Let me just -- I don't mean to cut off your answer, but I just want to stop you because I'm talking about prices that the government directed manufacturers to report specifically.

A. Oh, excuse me. No, this is actually the only example I know of the Medicare/Medicaid officials directly telling the manufacturers what price to provide them for purposes of a rebate or anything else. The other were directed to the carriers and to the state governments.

(*Id*. at 863:18-866:4)

27. Abbott's PPD employees testified that they believed that they reported the prices that the pricing compendia wanted and in accordance with Abbott's use of the terms. (1/15/09 Lehn Dep. at 78:20-25, Ex. 3.)

(a) Joseph Fiske, Director of Pricing and Planning, testified:

A. The information that we reported to the data agencies was our WAC and our list price. Any changes to our WAC and list price, we did so in good faith with the expectation that that was the information we should be providing. Nobody told us to do anything differently than that, including Kay Morgan who certainly had the opportunity because she knew what our practices were.

(30(b)(6) Fiske Dep. at 166:24-167:7, Ex. 2.)

> * * * * *
>
> A. The pricing that we reported to the pricing compendia were the WAC and the list price -- the published WAC and list price, the -- the WAC price before any discounts to any of our customers, including the wholesalers. That was our practice. We always acted in good faith by doing that. Nobody ever told us that we should do anything differently than that.

(*Id*. at 195:7-14.)

> * * * * *
>
> The WAC price and the list price that we reported to the data agencies was a price that customers paid for our products. It was a price that was generally available in the marketplace. There was no intent to misrepresent anything.

(*Id*. at 197:2-6.)

> * * * * *
>
> (b) April Gerzel, a PPD Pricing Analyst testified:
>
> Q. Do you have any idea at all why Abbott was reporting prices to the compendia?
>
> Objection.
>
> A. I believe that's what our obligation was that they wanted us to report to them.
>
> Q. (BY MR. ANDERSON): How did you gain that understanding?
>
> A. Through my training, when I came to the position.
>
> Q. What was the obligation?
>
> A. To inform the pricing compendia of new product launches, price changes to list or WAC, or any discontinued products that we were no longer going to manufacture and sell.

(2/20/09 Gerzel Dep. at 44:24-45:13, Ex. 10.)

28. Kay Morgan, mentioned in Mr. Fiske's testimony quoted in the previous paragraph, worked at Abbott from 1975 to 1999, and then went to First DataBank and served as Manager of

Editorial Services there, where she was responsible for the pricing information published by First DataBank until she left in 2005. (8/27/07 Morgan Dep. at 27:17-20; 28:19-29:11, Ex. 20.)

29. Abbott PPD understood that the compendia set AWPs based on surveys of wholesalers. (30(b)(6) Fiske Dep. at 104:17-105:5, Ex. 2.)

30. Abbott PPD employees did not understand WAC or AWP to mean any sort of average of net transactional prices. (1/22/09 Pavlik Dep. at 32:23-33:15, Ex. 1; 12/18/08 Arnold Dep. at 24:16-26:8, Ex. 21; 12/18/08 Kadish Dep. at 17:13-18:10, Ex. 22.)

31. Abbott PPD employees did not know, or have any reason to believe, that they were supposed to report prices that were the "best estimate of the prices generally and currently paid by providers for a drug." (30(b)(6) Fiske Dep. at 60:10-23; 244:9-245:8; 252:2-253:12, Ex. 2.)

32. While Abbott PPD submitted List Prices and WACs for the Ery drugs, the compendia actually calculated and set the AWPs. (30(b)(6) Fiske Dep. at 143:23-144:1, 175:16-23, Ex. 2.)

33. Occasionally, Abbott personnel would put "est. AWP" on some forms. (2/19/09 Parker Dep. at 58:16-23; 70:9-15, Ex. 6; 1/22/09 Pavlik Dep. at 57:2-13, Ex. 1.) Some Abbott PPD employees observed a historical mathematical relationship between WAC and AWP. (1/15/09 Lehn Dep. at 40:12-41:2, Ex. 3.) The employees understood that the compendia, not Abbott, controlled the AWPs that were published. (1/22/09 Pavlik Dep. at 61:23-62:1 (Abbott sets WAC and List Price, but not AWP), Ex.1.) Abbott PPD specifically refused to verify the accuracy of the compendia's AWPs and told the compendia on several occasions that it never intended to control the AWP published by the compendia. (*See* Gerzel Ex. 10 ("Abbott does not control how Red Book does its business nor does Abbott provide AWP or a calculated markup to establish an AWP. Consequently, Abbott concluded that there was no need to respond to Ms. Voeck's April

2003 letter. Abbott trusts that Red Book will continue to conduct its business as it sees fit.", Ex. 23); 10/20/09 Gerzel Dep. at 127:5-129:14, Ex. 10; 30(b)(6) Fiske Dep. at 142:18-144:12, Ex. 2; 1/15/09 Lehn Dep. at 189:7-18, Ex. 3 (PPD never tried to change the AWPs published in the compendia "[b]ecause we didn't have anything to do with AWPs.").)

II. MEDICAID PAYMENTS FOR ERYS WERE NOT CALCULATED FROM REPORTED PRICES.

A. The FULs That Included The Erys Were Not Based On The Ery AWPs And Often Were Not Based On Reported Prices At All.

34. On January 15, 1969, new regulations were enacted providing for federal financial participation in state medical assistance programs. (31 Fed. Reg. 1243, Ex. 24.) According to these regulations, payments for prescription drugs could be made under this program at a rate "defined by the State agency." (*Id*. at 1244.)

35. The Federal Upper Limit ("FUL") program was established by the Secretary of Health and Human Services in 1987. (*See* 52 Fed. Reg. 28648, 28653 (July 31, 1987), Ex. 25.) The Secretary established the FUL program to allow "the Federal and State governments to take advantage of savings that are currently available in the marketplace for multiple source drugs . . . [while] maintain[ing] State flexibility in the administration of the Medicaid program." (*Id.*)

36. According to federal regulation, A FUL is established for a drug if:

> (1) All of the formulations of the drug approved by the [FDA] have been evaluated as therapeutically equivalent in the most current edition of their publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*;
>
> (2) At least three suppliers list the drug [in the FDA publication] based on all listings contained in current editions [or updates] of published compendia of cost information for drugs available for sale nationally.

(52 Fed. Reg. at 28658, Ex. 26.)

37. The FUL represents an amount set by CMS that caps what an agency may reimburse pharmacies, not including the dispensing fee, for a drug on the FUL. FULs are set by CMS. (52 Fed. Reg. at 28658, Ex. 26

38. FULs were in place for Medicaid payments to pharmacies for dispensing multisource, oral erythromycins. (Reisetter Report ¶ 48, Ex. 11; Redbook listings (noting the FUL price (as "HCFA") for Erys, Ex. 27; Ven-A-Care 30(b)(6) Dep. at 221:3-19, Ex. 28.)

39. FULs are to be set by computing a price "equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or in the case of liquids, the commonly listed size." (52 Fed. Reg. at 28653, Ex. 29.) Because the Ery AWPs were never the lowest reported number (even just compared to the Ery WACs), and the FULS, therefore, were never based on the Ery AWPs.

40. Sue Gaston was the CMS employee responsible for setting FULs from April 1991 through February of 2003. (1/24/08 Gaston Dep. at 40:7-40:10, Ex. 30.) Gail Sexton was the CMS employee responsible for setting FULs beginning in 2004. (05/20/08 Sexton Dep. at 49:13-50:21, Ex. 31.)

41. According to Ms. Gaston, CMS utilized a computer program and then a manual review to establish the FULs. (1/24/08 Gaston Dep. at 232:22-234:6, Ex. 30.)

42. Ms. Gaston further testified that the manual review process was used to determine whether the price was "truly available or not" and whether or not "you should follow up and see if it's available." (*Id*. at 229:8-230:14.)

43. According to Ms. Gaston, CMS did not always set the FUL based on the lowest reported price of the drug for which the FUL capped payment. For example, CMS disregarded published prices and set a higher FUL to in response to feedback from the pharmacy community or to assure Medicaid patients access to pharmaceuticals. (3/19/08 Gaston Dep. at 451:12-451:19, 498:16-499:9, Ex. 32.)

44. CMS officials received feedback from members of the pharmacy community and from State Medicaid agencies about: "whether they felt that the FUL prices or the drugs were correctly on the FUL list or needed [to be] adjust[ed]"; whether the product was "available"; and whether "the pricing appears to be either too low or too high." (*Id*. at 433:14-434:8, 435:8-435:11, Ex. 32; 5/20/08 Sexton Dep. at 110:14-110:21, Ex. 31.)

45. The process CMS utilized in establishing FUL prices was recently the subject of a tutorial hearing before Judge Saris in the New York Counties Consolidated Cases. During that hearing, the Court acknowledged that CMS violated the regulation establishing the process for CMS to set FULs. (July 8, 2009 Tutorial and Motion Hearing at 32:24-33:5, Ex. 33.)

46. A FUL for an erythromycin drug prevented a pharmacy from increasing its Medicaid payment by submitting a claim for an erythromycin with a higher AWP than another generically equivalent erythromycin had. (5/1/09 Perri Dep. at 109:3-20, Ex. 12; *see also* 30(b)(6) Fiske Dep. at 164:1-6 ("You have to keep in mind that the erythromycin products were multisource pharmaceuticals and often third-party payors, whether it be government agencies or others, don't reimburse based off of an AWP. They actually reimburse based on some MAC formula.") Ex. 2.)

B. The MACs That Included The Erys Were Not Based On The Ery AWPs And Often Were Not Based On Reported Prices At All.

47. State Maximum Allowable Costs ("MACs") similarly capped Medicaid payments to pharmacies. (Steven Young, Ph.D. Report at ¶ 46 ("[A]t least twenty states performed their own determination of a MAC price to be paid for pharmacies for erythromycin."), Ex. 34.) At least 12 of these States looked at information other than reported numbers.

48. In this case and the DOJ case, discovery was conducted with respect to approximately half the state Medicaid agencies. Erythromycin products were found on the following 22 MAC lists from those states: Alabama, Arkansas, California, Delaware, Florida, Georgia, Idaho, Illinois, Kentucky, Maryland, Michigan, Missouri, Nebraska , North Dakota, Ohio, Oklahoma, Oregon, South Carolina, Vermont, Virginia, Washington, Wyoming. (*See* Collection of MAC lists, Ex. 35; *see also* testimony from State Representatives: 12/2/08 Roxane Homar Dep. at 340:15-342:20 (Wyoming), Ex. 36; 12/11/08 Frank Tetkoski Dep. at 126:2-6 (Maryland), Ex. 37; Ex. 38 (Maryland 14); 12/2/08 Gary Cheloha Dep. at 308:3-8 (Nebraska), Ex. 39.)

49. State Medicaid programs used pricing information beyond manufacturers' prices reported in the pricing compendia to establish the MACs, such as:

(a) Invoice prices provided by pharmacies. (*See* Ohio: 12/15/08 Reid Dep. at 160:19-161:20, Ex. 40; Arkansas: 12/10/08 Bridges Dep. at 65:3-11, 244:14-245:9, Ex. 41; Maine: 3/26/2008 Walsh Dep. 97:20-98:14, Ex. 42.)

(b) Direct surveys of pharmacies and wholesalers. (*See* Nebraska: 12/02/08 G. Cheloha Dep. at 130:10-132:17, Ex. 39; Washington: 11/24/08 Hautea-Wimpee Dep. at 212:7-213:1 230:20-21, Ex. 43; North Dakota: 12/12/08 Joyce Dep. at 128:21-129:20, Ex. 44; Wyoming: 12/2/08 Homar Dep. at 214:6-12, Ex. 36.)

(c) Review of wholesaler catalogs and price lists: (*See* Tennessee: 3/12/08 Sullivan Dep. at 106:18-107:22, Ex. 45; Maryland: 12/09/08 J. Fine Dep. at 203:8-204:19, Ex. 46.)

50. Many state Medicaid officials confirmed that AWPs were not used to set MAC prices. (*See* Arkansas: 12/10/08 Bridges Dep. at 248:5-15, Ex. 41; Tennessee: 3/12/08 Sullivan Dep. at 115:20-116:10, Ex. 45; Maryland: 12/9/08 Fine Dep. at 320:2-10, 321:10-14, Ex. 46; 12/11/08 Tetkoski Dep. at 129:17-21, Ex. 37; Washington: 11/24/08 Wimpee Dep. at 226:16-227:9, Ex. 43; North Dakota: 12/12/08 Joyce Dep. at 109:20-110:10, 128-21-129:20, Ex. 44.)

51. For many states, MAC pricing (and pricing in general) was influenced by policy determinations and a give-and-take with providers. (*See, e.g.* Colorado: 12-15-08 Chapman Dep. at 46:1-17, 334-35, Ex. 47; Georgia: 12/15/08 Dubberly Dep. at 75:7-75:19, Ex. 48; Hawaii: 4/29/08 Donovan Dep. at 188:2-21, Ex. 49; Nebraska: 12/2/08 Cheloha Dep. at 125:20-126:12, Ex. 39; Wisconsin: 10/30/07 Collins Dep. at 82:8-83:7, 85:22-86:4, Ex. 50; *see also* Hughes Report ¶ 75, Ex. 51.)

52. Many state Medicaid agencies allowed for a profit margin in their MAC prices. (*See, e.g.,* Indiana: 12/3/08 Shirley Dep. at 410:10-18 (Indiana Medicaid established its MAC prices at 20% above the actual acquisition cost), Ex. 52; Massachusetts: 6/14/07 Jeffrey Dep. at 96:5-13 (Massachusetts Medicaid included profit margin in its MAC prices "in order to induce" pharmacy participation), Ex. 53; Wyoming: 12/2/08 Homar Dep. at 231:17-232:10 (Wyoming Medicaid set MAC prices 40% above the average actual acquisition cost in order to include a "profit" and to cover the "cost of running business"), Ex. 36; North Carolina: 10/21/08 Weeks Dep. at 263:15-264:6 (North Carolina set MAC prices at 20% above actual acquisition cost.), Ex. 54; Minnesota: Myers & Stauffer Analysis ("SMACs are based on an informal survey of a few

retail pharmacies that have agreed to share their costs. *The State tries to include an average profit of about $7.00 for each prescription using SMAC*. This $7 includes the $3.65 dispensing fee. . . ."), Ex. 55; Nebraksa: Dey Ex. 911 (Nebraska structured its MAC program "to insure that the profit to the pharmacist to dispense the generic product is higher than that associated with dispensing the brand product."), Ex. 56.

C. FULs and MACs Eliminated The Possibility to Market The Spread

53. Ven-A-Care's marketing expert, Matthew Perri admitted that the establishment of MAC or FUL not based on company's published price would preclude marketing the spread.

> Q. Let me clarify one aspect. What the Arkansas program asked was of the pharmacist what price you're paying for it. So they weren't asking for an AWP or what do you read in a compendia. They were asking what price do you pay and they used that information to set the MAC. So they were asking --
>
> A. Excuse me. May I? They were asking what is your actual acquisition cost at the pharmacy level net.
>
> Q. Yes.
>
> A. Okay.
>
> Q. So the MAC was set based on that information. And then that served as the maximum cost. And so by setting what you've described as an inflated AWP, Abbott was not in fact impacting what the Maximum Allowable Cost would be under that scenario.
>
> MR. ANDERSON: Objection to form.
>
> BY MR. BERLIN:
>
> Q. Do you understand?
>
> A. With regard to that the MAC price, that would be used by the -- in this example by the Arkansas Medicaid program, that could be true, but the AWP prices that were reported would still influence to whatever extent other third-parties were reimbursing for these products.
>
> And then again, the actual level of prices that are reported by the pharmacists reporting their actual acquisition cost would need to

> be considered in conjunction with their net prices that they were paying once all rebates and incentives were filtered out. So without knowing exactly what these pharmacists reported, if they reported a net acquisition cost, net of all rebates and other incentives, then I could begin to agree with that statement.
>
> (5/1/09 Perri Dep. at 85:7-86:17)
>
> Q. If Ery is on a FUL, and again putting aside your example of where the pharmacy is going to call the physician and try to convince the physician to write another script, Abbott can jack up the price of its AWP until kingdom come, but that's not going to raise the price of the FUL, right?
>
> A. Yes.

(5/1/09 Perri Dep. at 103:17-104:1, Ex. 12.)

III. AWP HAS NEVER BEEN DEFINED, BUT HAS BEEN UNDERSTOOD UNIVERSALLY WITHIN THE GOVERNMENT AND THE INDUSTRY, AS MERELY A PUBLISHED NUMBER AND NOT AN ACTUAL AVERAGE OF WHOLESALE PRICES.

A. AWP Is An Undefined Term

54. To comply with Section 4556(c) of the Balanced Budget Act of 1997, Donna Shalala, Secretary of the Department of Health and Human Services, provided a "Report to Congress on The Average Wholesale Price For Drugs Covered Under Medicare" in 1999. (Ex. 57 (HHC902-0801 – 18).) In her report, Secretary Shalala compared the increase in AWPs reported by First Databank with inflation. (*Id.* at HHC902-804.) Ms. Shalala report included the following language:

> The AWP is not a well-defined concept nor is it regulated in any way. OIG reports that AWP is set by manufacturers as a suggested price and published in various commercial sources. However, it is not truly an average of wholesale prices because very few purchasers actually pay this amount.
>
> * * *
>
> Conclusions are further obfuscated by the OIG finding cited earlier in this report that, as an unregulated, suggested price, typically set by the manufacturer, the AWP bears no consistent or predictable

> relationship to the prices actually paid by physicians and suppliers to drug wholesalers in the marketplace.

(*Id.* at HHC902-0803, 0809.)

55. HHS employees have repeatedly testified that AWP is not defined or regulated in any way. For example:

(a) Robert Vito, one of the OIG's head auditors in charge of assembling OIG reports on AWP, stated that AWPs could not even be properly audited by the OIG because there is no regulatory or statutory definition that defines what it is, much less what a manufacturer must do: "I've testified before Congress that AWP is not defined, not auditable . . . ." (6/20/2007 Vito Dep. at 399:9-22, Ex. 58.)

(b) Dennis Smith, CMS's most senior official with respect to Medicaid testified that "[AWP] is not further defined in law or regulation . . . . There is no definition, precise." (3/27/2008 Smith Dep. at 430: 2-7, Ex. 59.)

(c) Thomas Scully served as CMS Administrator from May 2001 through January 2004. (5/15/07 Scully Dep. at 97:12-15, 50:8-13, Ex. 60.) Mr. Scully testified regarding how CMS interpreted the term AWP:

> Q. And was it your understanding that the, that the AWP that CMS was using as the benchmark for reimbursement was the AWP that was published in the compendia?
>
> A. For the most part, it was my understanding that the standard practice was that 95 percent of AWP was the AWP that was published in the Red Book.
>
> Q. And that's what you understood the law and regulations to require?
>
> A. That's what I understand at the time. At the time, that's what I believe the law and regulations required.

(*Id*. at 105:17-106:06.) Mr. Scully also testified that AWP is "air", "it's nobody's fault, it's a stupid policy." (*Id.* at 195:3-5.) Mr. Scully provided the further testimony:

> I don't blame anybody for doing what they did. The government created stupid incentives. But it was an insane policy. And so, understanding it from both sides, I was determined to fix.

(7/13/07 Scully Dep. at 493:14-18, Ex. 17.) Thomas Scully also testified regarding the definition of AWP set forth in the United States' Complaints in the DOJ Actions:

> Q. Okay. Now, this was a complaint that was signed the 22nd day of August, 2006, and on paragraph 40, in the first sentence, it says, AWP is used to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail customer, who then administers it to a patient; do you see that?
>
> A. Yes.
>
> Q. That's not what AWP was viewed as, that's not the view of CMS as to what AWP was, is it?
>
> MR. NEAL: Objection as to from.
>
> By MR. ESCOBAR:
>
> Q. Is it?
>
> MR. NEAL: This is not a 30(b)(6), this is not a 30 (b)(6) deposition. You can answer.
>
> A. No, I don't think that's what AWP is commonly considered to be, I think that's an inaccurate description.
>
> Q. In fact, that's a completely inaccurate statement of AWP; right?
>
> MR. NEAL: Objection as to form.
>
> A. I think it's probably a poor description, yes.
>
> Q. Because it's not accurate?
>
> A. Yes.

(*Id*. at 709:20-711:02.)

(d) Charles Booth, former Director of HCFA's Office of Payment Policy conceded that he never understood AWP to be a calculated average of wholesale prices. (10/29/2007 Booth Dep. at 518:14-18, Ex. 61.)

(e) Elizabeth Richter, former Acting Director of the Center for Medicare Management noting that no HCFA/CMS administrator thought that published AWPs represented the average price at which wholesalers sold drugs to their customers. (12/7/07 Richter Dep. at 68:3-13, Ex. 62.)

(f) Larry Reed, Technical Director, CMS Medicaid Division of Pharmacy, agreeing that AWP was like a "sticker price" and was referred to as "ain't what's paid"). (9/26/07 Reed Dep. at 260:11-261:5, Ex. 63.)

56. T. Mark Jones, one of Ven-A-Care's representatives, provided the following testimony:

> Q. Quote, "During that meeting, we were shocked by certain statements made by certain HCFA officials concerning their understanding that the term AWP had never been legislatively or administratively defined by the Federal Government," close quote. Was that statement made during your September 1995 meeting?
>
> A. I remember it being said that AWP isn't defined. That's how I remember these. I don't remember it being legislatively or administratively defined.
>
> Q. The people who were making that statement, they were the people at HCFA who were responsible for administering the Medicare and Medicaid programs. Correct?
>
> A. To the best of my recollection, I remember it being Sheree Kanner who was the general counsel for HCFA.
>
> Q. You remember it was Ms. Kanner who said that AWP --
>
> A. That's how I remember it, yes.
>
> Q. And as the office of general counsel, you understand that Ms. Kanner was HCFA's lawyer. Correct?

MR. BREEN: Objection to form.

THE WITNESS: Yeah. I guess.

BY MR. COOK: Q. Did you disagree with Ms. Kanner about whether AWP had ever been legislatively or administratively defined by the Federal Government?

A. I don't remember if I had any dialogue with her over it.

Q. Did Mr. Lavine disagree with Ms. Kanner at this meeting?

A. I don't remember it being a big dialogue. I think it was a statement that I remember.

Q. Do you remember anybody at that meeting disagreeing with Ms. Kanner that AWP had never been legislatively or administratively defined by the Federal Government?

A. No.

(3/19/08 Jones Dep. at 551:9-553:8, Ex. 64.)

57. And in 2001, GAO publicly announced that the "*term AWP is not defined in law or regulation*, so the manufacturer is free to set AWP at any level, regardless of the actual price paid by purchasers." (Ex. 65 at 4 (GAO Report, "Medicare Part B Drugs: Program Payments Should Reflect Market Prices").)

B. Neither The Government Nor The Industry, At Any Point During The Relevant Claims Period, Has Ever Understood AWP As An Actual Average Of Any Prices

58. In September 1984, the Department of Health and Human Services Office of Inspector General ("HHS-OIG" or "OIG") issued a report titled "Medicaid – Limitation on Payments for Drugs." (Ex. 65.) According to the report: "Within the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price." (*Id*. at 10.193.)

59. In September of 1989, OIG issued a Management Advisory Report, titled (Ex. 67 (Dey Ex. 46).) That report stated that "generic drugs can be purchased at a greater discount than

Brand name drugs – the discounted AWP had less impact on generic drugs." (*Id*. at 6.) The OIG also noted that "AWP is not a meaningful figure." (*Id*. at 1.)

60. In a December 1997 radio address, President Clinton urged Congress to adopt his proposed legislation. According to President Clinton, providers who were being reimbursed at AWP were "paying just one tenth" of that to purchase some drugs. (Ex. 68 (Abbott Ex. 55).) President Clinton remarked that AWP spreads of up to 1000% weren't "even illegal; *they're just embedded in the practices of the system.*" (*Id*. emphasis added.)

61. Numerous state officials testified and other state evidence showed that state Medicaid officials understood that compendia AWPs were not a reliable source of market prices for generic drugs, and that spread were much greater for generic drugs than for brand drugs:

(a) Jerry Wells, former Pharmacy Program Manager in Florida testified that he knew by at least 1987 that AWPs for generics could exceed acquisition cost by "80 to 90 percent" and that the difference between AWPs and market prices for generics was "all over the map." (12/15/08 Wells Dep. at 206:2-208:21, 266:9-267:4, 339:13-341:2, Ex. 69.)

(b) Sandra Kramer, former Policy Analyst for Michigan Medicaid, testified that, since 1992, she understood that for generic drugs "AWPs were upwards of 500 percent above acquisition costs." (3/25/08 Kramer Dep. at 84:14-85:20, 93:4-94:2, Ex. 70; *see also* Ex. 71 (Abbott Ex. 655); Ex. 72 (Abbott Ex. 656).)

(c) A 1994 document from Illinois Medicaid, which discussed a proposal to change the reimbursement methodology for prescription drugs, stated: "AWP has become virtually meaningless as a real number, particularly for multi-source drugs." (Ex. 73 (Roxane Ex. IL 5).) A 1995 document from Illinois Medicaid referred to AWP as "most meaningless for generic drugs." (Ex. 74 (Roxane Ex. IL 7).) In an October 4, 1995 response letter to a survey

from South Dakota Medicaid regarding the relationship between AWP and pharmacy cost, Illinois Medicaid stated that neither "the FUL or AWP mean anything for generic drugs." (Ex. 75 (Roxane Ex. IL 8).)

(d) Ohio's Robert Reid testified that he saw a "clear distinction between trade name drugs and generic drugs" and he knew it was "not uncommon for there to be a wide, wide disparity between AWP" and acquisition cost for generics. (12/15/08 Reid Dep. 109:7-110:13, Ex. 40.)

(e) Benny Ridout, North Carolina's Medicaid Pharmacy Director from 1972 to 2000, testified that he knew "all through [his] career" that the "brand[] [AWPs] always had less markup on them than the generics." (12/5/2008 Ridout Dep. at 36:6-37:19, 50:4-11; Ex. 76.)

(f) By the mid-1990s, Oklahoma's Nancy Nesser knew of a "wide difference" between AWP and acquisition cost for generics. She testified that "[i]t wasn't like, with the brand name where you could –you can see it's consistent…If you pulled two-even of the same generic drug, the-there's no consistency between the AWP and the acquisition." (12/12/08 Nesser Dep. at 54:8-22, Ex. 77.)

IV. FEDERAL AND STATE PAYORS WERE WELL AWARE OF THE SPREADS BETWEEN THE ERYS' AWPS AND AVERAGE NET TRANSACTION PRICES

62. In September 1984, the HHS-OIG issued a report titled "Medicaid – Limitation on Payments for Drugs." (Ex. 65.) Included in this report was a comparison of the Bluebook AWP and the 70th Percentile Price based on data collected from an audit of pharmacy invoices for EES 400® tabs. According to the report, the AWP for EES 400® was $21.95 and the 70th Percentile Price per Audit was $16.49, resulting in a spread of 33%. (*Id*. at 10.203.) The report also listed prices generally paid by pharmacies in different states. (*Id*. at Schedule V.) According to the

report, the median price paid by pharmacies in Massachusetts for EES 400® tabs was $14.06, resulting in a spread of 56%.[1] (*Id*.)

63. On September 17, 1986, the State of Colorado Department of Social Services wrote to HCFA, the federal agency responsible for Medicaid regarding proposed regulatory changes concerning maximum limits for generic drugs, and warned that pharmaceutical manufacturers were using spreads on drug prices as a "marketing tool": "Published data in Red Book or Blue Book should be used with caution. Market surveys of various brands of generics should be used to verify accuracy of the data. . . . Submission of artificially high AWP prices has been used as a marketing tool by the generic companies to sell their products." (Ex. 78 at 4.)

64. On July 5, 1987, the Lexington Herald-Leader published an article titled "Drug Industry Overcharging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars." (Ex. 79.) The article stated that "Medicaid programs across the country are making millions of dollars in overpayments because of flaws and abuses in the way they buy prescription drugs for the poor." (*Id*. at 1.) The article stated that "[t]he system is distorted even further by drug companies that publish prices that are dramatically higher than the prices they actually charge pharmacies." (*Id*.) In one example, the article stated that, as a result of a 1985 survey, Texas Medicaid officials learned that "one brand of penicillin . . . had a Red Book price of $100 'but pharmacists were buying it all day long for $30.'" (*Id*. at 7.) In another example, the article stated that Kentucky Medicaid officials "discovered that [an arthritic medication] was being sold to pharmacies for only 8.88 cents a tablet—47% below the published Average Wholesale Price." (*Id*. at 4.) The article also discussed a "sales technique called 'playing the spread,'" noting that a large "spread, or

[1] The spreads represented in Ven-A-Care's Complaint are exaggerated by 100%. For example, based on Ven-A-Care's method of calculating spread in the Complaint's Exhibit A, even if a drug's AWP is only 5% more than the "relator's cost," Ven-A-Care would claim that drug has a 105% spread. For consistency and to enable valid comparisons, this brief will utilize a proper calculation of spread ((AWP-AAC)/AAC or (AWP/AAC)-1.0).

difference, between the [AWP] and the actual price" meant that "a pharmacist buying that drug could make a larger profit." (*Id*. at 4-5.) The article stated that some "companies actually advertised that they had a better spread," and "many companies routinely list Average Wholesale Prices and 'your price' in their catalogs to show the spread." (*Id*. at 5.) The article indicated that previous attempts to change the system had "met bitter resistance from the National Association of Retail Druggists" and other groups, who "led the fight to force the federal Health Care Financing Administration . . . to retreat from proposed changes in 1985 that came up after the inspector general's audit discovered the overpayments." (*Id*. at 8-9.)

65. In March 1991, the HHS-OIG issued a report entitled "Comparison of Reimbursement Prices for Multiple-Source Prescription Drugs In the United State and Canada." (Ex. 80.) This report focused on the "most commonly used drugs" and found: "over half of the commonly used drugs had lower prices in Ontario." (*Id.* at ii.) According to the report, the Ontario price for Erythromycin Tab 250 mg was 55.3% lower than the HFCA FUL. (*Id*. at B-2.)

66. On July 31, 1992, the Energy Commerce Committee of the U.S. House of Representatives held a hearing to discuss "Bills to Amend the Public Health Service Act and the Social Security Act to Establish Limits on Certain Drug Prices." (Ex. 81.) John M. Rector, Vice President of Government Affairs and General Counsel for the National Association of Retail Druggists ("NARD"), submitted a statement at the hearing. (*Id.* at 280.) NARD also submitted a comparison of the contract prices (available to members of its organization) and published AWPs. (*Id*. at 302-310.)

67. Several versions of Abbott's Erys at issue in this case were on NARD's list presented to the U.S. Congress, including EES 400® TABs, EES® 200 liquid, EES 400® liquid, Ery-TAB® 250 mg tabs, Ery-TAB® 333 mg, and Ery-TAB® 500 mg. (*Id*.) The price lists show

discounts for these drugs ranging from AWP-56% to AWP-86% (spreads of 127% to 614%). (*Id.*) These spreads, publicly disclosed in 1992, equal or exceed the spreads alleged by Ven-A-Care on the same drugs a decade later. The following table compares the spreads shown in this 1992 Congressional Report and the spreads alleged in Ven-A-Care's Complaint.

Drug	1992 Congressional Report AWP	1992 Congressional Report Contract Cost	Spread Disclosed in 1992	Ven-A-Care Alleged Spread
E.E.S.® 400 tabs	$104.12	$46.25	125%	58%
E.E.S.® 200 liquid	$19.59	$8.00	145%	64%
E.E.S.® 400 liquid	$36.49	$15.45	136%	79%
Ery-Tab® 250 mg tabs (100)	$23.75	$3.51	577%	178%/249%
Ery-Tab® 250 mg tabs (500)	$112.81	$17.43	547%	242%
Ery-Tab® 333 mg tabs (100)	$34.97	$4.78	632%	147%/218%
Ery-Tab® 333 mg tabs (500)	$166.12	$23.78	599%	211%
Ery-Tab® 500 mg tabs (100)	$40.10	$12.78	214%	132%/154%
Erythrocin® 250 mg (500)	$65.31	$24.75	164%	109%
Erythrocin® 500 mg (100)	$24.86	$11.89	109%	98%
Pediazole® suspension (100 ml)	$13.99	$4.23	231%	69%
Pediazole® suspension (200 ml)	$27.29	$8.37	226%	69%
Pediazole® suspension (250 ml)	$33.61	$10.50	220%	70%

68. In August 1994, at HCFA's request, the Office of Inspector General (the "OIG") commenced an audit surveying drug prices. (6/24/08 Chesser Dep. at 66:1-9; 89:2-4, Ex. 82.) The results of this study were published in a 1997 OIG report titled Medicaid Pharmacy – Actual

Acquisition Cost of Generic Prescription Drug Products. (*Id.* at 87:19-88:11.) The objective "was to develop a nationwide estimate of the discount below AWP at which pharmacies purchase generic drugs." (*Id.*) As part of its study, the OIG collected over 9000 invoice prices for generic drugs. (*Id.*) Based on the audit, the OIG "estimated that, on average, actual acquisition cost of generic drugs was 42.5 percent below AWP" resulting in a 74% spread. (*Id.*) In its comments to the report, HCFA concurred with the OIG's findings and stated that "[t]he findings shown in the report confirm the belief shared by many states that the pharmacy's actual generic drug acquisition costs are much less than the prices paid by many states to the pharmacies." (*Id.* at App. 3, Pg. 2.) The OIG Working Files reflect audits of actual invoices containing Ery-Tab prices. (Working Files, Ex. 83.)

69. On June 10, 1996, *Barron's* published an article entitled "Hooked on Drugs," which detailed not only an alleged spread between Abbott's reported AWP and its prices for certain of its generic drugs, but also stated that drug manufacturers, including Abbott, employed "drug salespeople . . .[that] let[] the doctor know that his product has a bigger spread between AWP and the real price than any other generic firm." (Ex. 84 at 3.)

70. In March 1997, various representatives of state Medicaid programs and an HHS-OIG investigator, Paul Chesser, attended a Medicaid Pharmacy Administrators Symposium in Asheville, North Carolina. (Ex. 85.) At least one meeting was held to obtain input from state Medicaid administrators about basing rebates on AWP rather than AMP. (*Id.* at 1.) The record of discussion notes that one reason offered in support of basing rebates on AWP was "that those drug manufacturers that play games with AWP (overstate AWP for marketing purposes) would immediately lower their AWPs to a more realistic level."

71. In May 1998, an OIG report titled "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs" reiterated that "[b]ecause AWP is usually used as a basis for reimbursement at the pharmacy level, manufacturers can use it as a marketing tool to gain market share." (Ex. 86 at 5.) This report goes on to acknowledge that "[t]he drug industry currently treats AWP as a published list price rather than a true wholesale price." (*Id*.)

72. In 1998, under contract from the State of Idaho, Myers and Stauffer prepared a report analyzing the acquisition cost of prescription drugs in the state of Idaho. (Ex. 87 at 4.) Myers and Stauffer utilized invoices collected from studies of Arkansas and Kentucky and weighed the data to Idaho Medicaid utilization. (*Id.*) This report found that the "average discount from AWP for multi-source drugs was 65%. (*Id.* at 5.) The report also included a table of "Idaho Weighted EAC Discounts." This table included Ery-TAB (NDC 00074632013) and listed its AAC and the AWP. (*Id.* at 18.) According to this report, the invoices collected from pharmacies indicated that the average price paid for Ery-TAB was AWP-65.5%, which is a 185% spread. (*Id*.)

73. In 1998, under contract from the Kentucky Department for Medicaid Services, Myers and Stauffer prepared a report on the cost of dispensing prescription medications to Kentucky Medicaid recipients. ("A Survey of Dispensing Prescriptions and Estimated Acquisition Cost in the State of Kentucky" Ex. 88 at 1.) This report found that pharmacies were able to obtain discounts from multi-source drugs that had a MAC price at a discount of AWP-72.6%, which is a spread of 264%. (*Id*. at 22.)

74. In March 1999, under contract from the Wyoming Division of Health Care Financing, Myers and Stauffer prepared a report titled "A Survey of Dispensing and Estimated

Acquisition Costs of Pharmaceuticals in the State of Wyoming." (Ex. 89.) According to this report, the actual acquisition cost of multi-source drugs that had a MAC price, had an average discount of AWP- 73.7%, which is a spread of 280%. (*Id.* at 23.) Ery-Tab ® (NDC 00074632013) was included in this study. (*Id*. at 21.)

75. In 1999, under contract from the Louisiana Department of Health and Hospitals, Myers and Stauffer prepared a report, titled "A Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the State of Louisiana" analyzing the pharmacy dispensing costs and drug acquisition costs for providers serving Louisiana Medicaid beneficiaries. (Ex. 90.) This report found that pharmacies were obtaining a discount of AWP-45.5% through AWP-62.8% for multi-source drugs. (*Id*. at 42.)

76. On November 29, 2001, the HHS-OIG published "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Texas Health and Human Services Commission." (Ex. 91.) This report stated that the average pharmacy acquisition cost for generic drugs was AWP-62.84% and WAC-26.13%. (*Id.*.)

77. On March 14, 2002, the HHS-OIG published "Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products." (Ex. 92.) This report found that "there is a significant difference between pharmacy acquisition cost for generic drugs and AWP." The estimated actual acquisition cost was 65.93% below AWP.

78. In September 2002, the HHS-OIG published "Medicaid Pharmacy Additional Analysis of the Actual Acquisition Cost of Prescription Drug Products." This report stated that multisource drugs with established FULs were purchased on average at AWP-72.1%, or a spread of 258%. (Ex. 93.)

79. In 2002, under contract from the California Department of Health Services, Myers and Stauffer prepared a report titled "A Survey of Acquisition Costs of Pharmaceuticals in the State of California." (Ex. 94 at 3.) This Report found:

> Findings from the study indicate that the current pharmacy ingredient reimbursement rate of AWP less 5% provides payments in excess of the costs actually incurred by California pharmacies in acquiring pharmaceutical products for Medi-Cal recipients. In fact, the acquisition cost study findings indicate that for a "typical" prescription, a pharmacy's margin on ingredient reimbursement is approximately $10. These margins on ingredient cost must be considered in tandem with an analysis of pharmacy dispensing cost and dispensing fee reimbursement in order to fully evaluate the issue of the adequacy of Medi-Cal pharmacy reimbursement.

(*Id*. at 4-5.)

80. State Medicaid officials had knowledge of spreads between acquisition cost and published AWPs, that AWPs were not a reliable source of market prices for generic drugs, and that spreads were much greater for generic drugs than for brand drugs

(a) Alaska: (8/19/08 Campana Dep. at 93:15-99:7; 721:8-14, Ex. 95.)

(b) Arkansas: (12/11/08 Bridges Dep. at 358:20-359:10, Ex. 96.)

(c) California: (3/19/08 Gorospe Dep. at 223:10-224:12; 240:1-8; 593:20-595:5, Ex. 97.)

(d) Colorado: (12/15/08 Chapman Dep. at 107:9-08:4; 222:22-223:10, Ex. 47.)

(e) Delaware: (12/09/08 Denemark Dep. at 268:1-269:3, Ex. 98.)

(f) Florida: (12/15/08 Wells Dep. at 339:13-341:2, Ex. 69.)

(g) Georgia: (12/15/08 Dubberly Dep. at 299:2-22; 290:11-292:18; 76:1-9, Ex. 48.)

(h) Illinois: (11/18/08 Parker Dep. at 202:8-21, Ex. 99.)

(i) Indiana: (12/2/08 Shirley Dep. at 236:18-238:5, Ex. 100.)

(j) Louisiana: (3/31/08 Terrebone Dep. at 184:19-185:15; 117:2-118:10, Ex. 101.)

(k) Maine: (3/26/08 Walsh Dep. at 147:6-13; 129:9-17, Ex. 42.)

(l) Maryland: (12/11/08 Tetkoski Dep. at 159:15-19, Ex. 37.)

(m) Michigan: (3/25/08 Kramer Dep. at 84:14-85:20; 93:5-94:2, Ex. 70.)

(n) Minnesota: (3/14/08 Wiberg Dep. at 16:10-21:1, Ex. 103.)

(o) Nebraska: (12/2/08 Cheloha Dep. at 224:12-226:17; 235:21-236:10, Ex. 39.)

(p) New Hampshire: (10/29/08 Clifford Dep. at 156:18-157:10, Ex. 104.)

(q) New Jersey: (12/2/08 Vaccaro Dep. at 170:17, Ex. 105)

(r) New Mexico: (12/15/08 Stevens Dep. at 174:7-14, Ex. 106.)

(s) North Carolina: (12/5/08 Ridout Dep. at 36:6-37:19; 50:4-11; 54:4-55:15, Ex. 76.)

(t) North Dakota: (12/12/08 Joyce Dep. at 97:16-99:5, Ex. 44.)

(u) Oklahoma: (12/12/08 Nesser Dep. at 54:8-22 ("wide difference" for generic and brand AWPs), Ex. 77.)

(v) Oregon: (12/15/08 Ketchum Dep. at 206:21-208:3, Ex. 107.)

(w) Ohio: (12/15/08 Reid Dep. at 109:7-110:13, Ex. 40.)

(x) South Dakota: (South Dakota September 27,1995 letter to Medicaid Pharmacy Administrators, requesting information "regarding the relationship between AWP and pharmacy cost.") (Abbott Hayashi 5, Ex. 108.)

(y) Rhode Island: (12/3/08 Young Dep. at 74:18-75:6; 256:13-260:19, Ex. 109.)

(z) Tennessee: (3/12/08 Sullivan Dep. at 110:13-102:18, Ex. 45.)

(aa) Virginia: (12/4/08 Hayashi Dep. at 149:22-150:8, Ex. 110.)

(bb) Vermont: (12/15/08 Rugg Dep. at 308:12-309:5, Ex. 111.)

(cc) Washington: (11/24/08 Wimpee Dep. at 206:15-210:7 (Old antibiotics, including Ery were acquired at discounts off of AWP in excess of 70%), Ex. 43.)

(dd) Wyoming: (12/3/08 Homar Dep. at 511:3-21 (AWP is higher than AAC, especially with generic drugs), Ex. 112; Roxane Wyoming Ex. 8 (Myers & Stauffer 1999 Survey showing AAC for generic drugs without a MAC was AWP-61.8%), Ex. 113.)

V. WITH FULL KNOWLEDGE, THE GOVERNMENT PAID SPREADS ON MEDICAID CLAIMS TO MEET POLICY GOALS

A. State Medicaid Pharmacy Payment Rates Were Negotiated With Politicians and Providers

81. Numerous state Medicaid officials explained that their programs arrived at pharmacy payment rates through a process of negotiation with legislators, governors, Medicaid officials and pharmacy providers. For example:

(a) When CMS asked in 2001 how Illinois came to its payment rate, Illinois informed CMS that "[o]ur drug cost methodology was derived via a two step approach which included 1) a thorough review of what other State's were doing and selecting the percentage off of AWP that was reasonable and 2) conducting negotiations with the Pharmacy Industry." (Ex. 114 (Abbott Ex. 769).)

(b) Idaho advised CMS that "[r]epresentatives from the state pharmacy association, hospital association, and retailer's association met with the Department numerous times to negotiate reimbursement rates for pharmacies." (Ex. 115 (Abbott Ex. 491).)

(c) New Jersey's Ed Vaccaro testified:

Q. During your time at Medicaid -- I'm sorry. Let me clarify it. During the 1990's, was that a concern to not incur the wrath of National Pharmacy Associations when you were developing reimbursement methodology?

A. I think there was a strategy implemented by the agency starting in the early 90's and forward that brought interested parties, advocates to the table before they made decisions that impacted, for example, reimbursement.

Q. When you say agency, which --

A. Advocates. We're talking about whether it be beneficiary advocacy groups or if we were going to somehow impose changes on eligibility. In the case of pharmacy we brought the associations to the table, including Pharma, when it was appropriate to do so, for the purpose of taking in their recommendations regarding reimbursement. For example, if we were proposing a certain level of reimbursement that we knew would be antagonistic we would ask them for their own proposals as alternatives to a change in reimbursement if indeed a goal was to save dollars. That kind of thing.

So what I think you're looking at here is in the 90's our efforts to try and, you know, reduce the rhetoric, if you will, from the various professional organizations, state or national, they would bring their national advocates in with them. Okay. And to try and work things out with interested parties ahead of time before we put something in place.

(12/2/2008 Vaccaro Dep. at 239:9-240:20, Ex. 105.)

* * *

Q. You testified earlier that in certain instances when New Jersey Medicaid had proposed reimbursement policies there were a variety of interests involved that were not affiliated with New Jersey Medicaid; is that correct?

A. That's correct.

Q. One of those interest groups were pharmacy associations; is that correct?

A. Yes.

Q. Would you agree that pharmacies had an interest in keeping reimbursement high?

A. Yes.

Q. And would you also agree that pharmacy advocacy groups place pressure on New Jersey Medicaid to keep reimbursement high?

A. Yes.

Q. You testified earlier also about the New Jersey Pharmaceutical Association; is that correct?

A. Yes.

Q. What types of, I'm sorry. What kinds of pharmacies do they represent?

A. Non chain pharmacies.

Q. Independent pharmacies; is that correct?

A. Yes.

Q. And do they represent only pharmacies located in New Jersey?

A. Yes.

Q. Do you know how many members are in that association?

A. I do not.

Q. Would it be in the hundreds?

A. Yes.

Q. Thousands?

A. Likely the thousands.

(*Id.* at 263:15-265:8.)

* * *

Q. So it's more than 50 percent of New Jersey pharmacies, independent, sorry, pharmacies?

A. It's not likely more than 50 percent because there are, I think there are five professional pharmacy organizations in the state. They sort of share who's going to be a member of what. Some are members of two associations. There's actually an association of chain drug stores, just for chain stores. That's only chain stores.

Then you have New Jersey Pharmacists Association, Garden State Pharmacy Owners, Independent Pharmacy Alliance. Those three share membership with, some pharmacies may be in some associations and not in others, so it might be in the hundreds, the high hundreds, maybe seven or eight hundred members are part of the Pharmacists Association. Same number might be in the Garden State Pharmacy Owners but there might be a duplicate membership.

Q. Okay. So you mentioned five pharmacy groups. Did they exist in the 1990's?

A. Yes.

Q. Under those names?

A. Yes.

Q. Early 1990's?

A. Definitely in mid 1990's.

Q. In 1990's?

A. I think they became stronger in the early 90's because of our transition between fiscal agents and the impact it had on the pharmacy community.

Q. I see. Were they present during any of the reimbursement proposals during the 1990, mid 1990's?

A. They would have been invited to sit with the division to talk about prospective proposals for the budget year coming up. Whether or not they actually were, you know, listened to or worked with is a different story but at least the invitation went out to have them talk to us so we would try to minimize any kind of negative impact to a policy change on them.

Q. So did New Jersey Medicaid, in fact, meet with any of these associations --

A. I would say yes.

> Q. -- during the mid 1990's?
>
> A. Yes, we would.
>
> Q. Do you recall which ones specifically?
>
> A. I think we met with them all as a group. We actually got to the point of inviting them all down together. Representatives from each organization would come down and sit and talk to us.

(*Id.* at 265:9-267:22.)

> * * *
>
> Q. Okay. Now, if you just go -- skip a paragraph and go to the paragraph that starts with: While -- while I believe, the second sentence he says, "I expect strong resistance from the provider community and a long and arduous negotiation." What does he mean by negotiation.
>
> A. As I indicated in testimony yesterday, we often, even back in the '80s, I would imagine, we often sat across the table from professional organizations in the State, professional pharmacy organizations, to discuss our intentions regarding changes in -- typically reimbursement, and this is an example of that.
>
> Q. Okay. And this is prior to Medicaid agencies submitting a State plan for approval?
>
> A. Yes.

(12/3/2008 Vaccaro Dep. at 414:9-415:3, Ex. 116.)

(d) North Dakota considered adequacy of payment levels when making overall changes to its payment formula and considered its reimbursement levels to be adequate as long as its paid the same amounts as Blue Cross Blue Shield North Dakota. (2/12/08 Joyce Dep. at 74:3-15, Ex. 44.)

(e) Arkansas's reimbursement methodology was affected by political considerations and "provider relations issues," such as opposition from industry lobbying and concerns by those in the pharmaceutical industry. (12/10/2008 Bridges Dep at 300:15-301:6, Ex. 41; 12/11/2008 Bridges Dep at 375:13-21, Ex. 96.)

(f) California's reimbursement policy was substantially affected by political negotiations, provider concerns, and lobbying by pharmacy groups. (12/3/08 Gorospe Dep. at 47:18-49:14, Ex. 117.)

(g) Michigan Medicaid was required to consult with providers regarding "any changes in reimbursement." (3/25/2008 Kenyon Dep. at 27:14-18, Ex. 118.)

(h) When asked to explain in 2003 how its reimbursement rate of AWP – 11% plus a dispensing fee of $3.91 was its "best estimate," Oregon provided the following statement to CMS: "The October 4, 2002 legislative Emergency Board directed the Department to increase the rates to institutional pharmacies to AWP - 11% plus dispensing fee of $3.91. Oregon submitted a SPA exactly as requested by this legislative body, and the documentation was previously submitted with SPA 02-06." (Ex. 119 (HHC020-0382).)

(i) New Hampshire's decision to begin discounting AWP by 12% in 1996 was reached after negotiations with pharmacies. (10/28/2008 Farrand Dep at 96:15:97-21, Ex. 120; 10/29/2008 Clifford Dep at 53:3-54:12, 55:13-56:12, 174:1-7, Ex. 104.)

(j) Alaska's decisions regarding reimbursement rates were also influenced by the political process and the state had to account for "political realities," and "whether or not [the state] has the political capital to force through a change." (8/19/2008 Campana Dep at 161:18-162:8, 163:14-164:4, Ex. 95.)

B. States Did Not Change Payment Rates Following Publication of OIG Reports

82. States did not change payment rates even after the OIG issued reports that states were paying at rates higher than the pharmacies' actual acquisition costs.

(a) In 1997, the OIG issued a report to Maryland pharmacists were purchasing generics at an average 41.9% discount below AWP. (Ex. 121 (Abbott Ex. 1064).) According to an internal Maryland document, Maryland considered changing its reimbursement rates but

decided not to due the "possibility of strong objections from pharmacy providers." (Ex. 122 (Abbott MD Ex. 30).)

(b) In 1996, Virginia Medicaid received and responded to OIG's 1996 survey of pharmacy acquisition cost for drugs reimbursed under the Virginia Medicaid program. (Ex. 123 (Roxane VA Ex. 5).) The report found that in Virginia the "overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 17.2 percent for brand name drugs and 45.1 percent for generic drugs." (*Id.*) In its response to a draft of the report, Virginia stated:

> DMAS appreciates the recommendation that Virginia Medicaid consider the results of this review as factor in any future changes to pharmacy reimbursement for Medicaid specific drugs in the state program. As stated, Medicaid reimbursement rates to pharmacy providers for covered outpatient prescription drugs consist of two components which are an amount representing the drug ingredient cost the acquisition cost and an amount representing the professional or dispensing fee. Normally the reimbursement cost is based on the lower of EAC estimated acquisition cost usual and customary or FUL Federal Upper Limit and Maximum Allowable Costs. As stated in the draft of these reviews the acquisition cost is just one factor involved in pharmacy reimbursement policy or methodology and with any change consideration should be given to other factors such as the following
>
> - Impact on recipient access to service
>
> - Present rebate allowances from pharmaceutical manufacturers to both federal and state programs
>
> - Provider specialty care or level of care such as Home Health providers Coordination of monitoring for recipients with compliance needs
>
> - Overhead costs for dispensing functions and record keeping
>
> This does not necessarily cover inclusively that factors that are involved in assuring that the Medicaid recipient receives the most efficient and cost effective health care available, but does emphasize that when one aspect of the equation is affected, all possible consequences should be considered.

(*Id.*). Virginia continued to use an EAC of AWP – 9% for both generic and branded drugs until 2002, when it was changed to AWP-10.25%. Virginia decided against changing its definition of EAC at that time it received the 1996 OIG Virginia report. Virginia's Bryan Tomlinson testified that Virginia received and reviewed the OIG report, but failed to change its reimbursement methodology. (11/3/2008 Tomlinson Dep. at 251:16-253:1, Ex. 184.)

(c) In 1996, Montana Medicaid received and responded to OIG's 1996 survey of pharmacy acquisition cost for drugs reimbursed under the Montana Medicaid program. (Ex. 127 (Abbott Ex. 327).) The report found that in Montana the "overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 16.2 percent for brand name drugs and 48.5 percent for generic drugs." (*Id.*) In its response to a draft of the report, Montana stated:

> It is important to note that the study did not investigate the payment of these services by Medicaid, only the cost of acquisition of the drug by the providers. We believe all states involved are concerned that if these numbers are directly compared to the discounted AWP method of Medicaid Pharmacy pricing, confusion and questions will arise. The two major factors that must also be considered if this comparison is done relate to the dispensing fee portion of the payment formula and the effect of Federal upper limit (FUL) pricing for generic drugs. No work was performed by the OIG to determine how total reimbursement for pharmacy services relates to the cost of providing the service.
>
> It is expected that when these results are published that the immediately concerns will be raised that pharmacy providers are being reimbursed more than the acquisition cost of the products and that changes should be made to the pricing formula to increase the discount on AWP. In order to address these concerns, states must do additional work to determine whether the cost to dispense is being accurately reimbursed and what effect the FUL pricing has on the discount for generic. In Montana we currently believe that the dispensing fee is below the cost to dispense because of the capon dispensing fees that is currently in place and has been for many years.

(*Id.*) Montana did not change its EAC formula (AWP minus 10%) in response to OIG's report.

(d) In 1996, Missouri Medicaid received and responded to a draft of OIG's 1996 survey of pharmacy acquisition cost for drugs reimbursed under the Missouri Medicaid program. (Ex. 126 (Roxanne Ex. 144).) The report found that in Missouri the "overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 18.5 percent for brand name drugs and 46.4 percent for generic drugs." (*Id.*) In its response to a draft of the report, Missouri stated:

> It was recognized in the 1990-91 study, as in your report, that ingredient cost is only one component to be considered in determining an appropriate pharmacy reimbursement level. Please note, that in September, 1991, the ingredient cost portion of the methodology was reduced to the amount reflected in the study; the standard professional dispensing fee was not raised to the recommended rate of $6.56 for independent pharmacies and $6.20 for chain pharmacies. The current standard dispensing fee of $4.09 remains below the established cost to dispense, as identified in the 1990-91 study ($5.69 for independent and $5.45 for chain pharmacies).
>
> One of the goals of DSS is to optimize the access to and the quality of health care services to the department's clients, partners and stakeholders. Toward that end, we must identify and take into consideration as many essential variables as possible in order to develop reimbursement policies that are adequate for providers and fair to Missouri taxpayers.

(*Id.*) Missouri did not change its EAC formula (AWP minus 10.43%) in response to OIG's report.

(e) In 1996, Florida Medicaid received and responded to OIG's 1996 survey of pharmacy acquisition cost for drugs reimbursed under the Florida Medicaid program. (Ex. 127 (Abbott Ex. 84).) The report found that in Montana the "overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 20.2 percent for brand name drugs and 41.5 percent for generic drugs." (*Id.*) In its response to a draft of the report, Florida stated:

> Comparing acquisition costs for Florida pharmacies to AWP, as an academic exercise, proves that pharmacies, like almost all retail businesses, purchase goods at some discount below suggested list prices, but does not provide an indication of need to change current reimbursement policy. . . .
>
> Restricting reimbursement to actual cost might have the unintended effect of discouraging purchase of promotional products and eventually shifting the market to single-source products which are universally much more costly. The average multi-source prescription costs Medicaid less than $11 and the average single -source product averages over $45.

(*Id.*) Florida did not change its EAC formula in response to OIG's report.

(f) In 1996, California Medicaid OIG's 1996 survey of pharmacy acquisition cost for drugs reimbursed under the Missouri Medicaid program. (Ex. 128 (Abbott Ex. 325).) The report found that in California the "overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 17.5 percent for brand name drugs and 41.4 percent for generic drugs." (*Id.*) California did not change its EAC formula (AWP minus 5%) in response to OIG's report.

(g) On October 22, 2002, CMS Administrator Tom Scully signed a decision memorandum on the subject of "Review of Medicaid Drug State Plan Amendments." (Ex. 129 (HHD830-000001-04).) That memorandum included the following language:

> We are writing to seek your approval for criteria to be used for reviewing state plan amendments (SPAs) that seek to change the payment rates for drugs. There are no explicit statutory provisions for payment rates for Medicaid drugs. States are required to set rates in accordance with regulations at 42 CPR 447.301-333.
>
> * * *
>
> Recent OIG reports estimate the actual acquisition cost of brand name prescription drug products nationally to be, on average, the average wholesale price (AWP) less 21.8 percent. The OIG recently revised this number to differentiate it between those single source brand name drugs without generic competition and those innovator multiple source brand name drugs with generic

competition. The OIG estimates that the single source brand name drugs cost. on average, AWP less 17.2 percent and the multiple source brand name drugs cost AWP less 24.4 percent. The OIG also studied generic drug discounts and found that the actual acquisition cost of generic prescription drug products nationally is, on average. AWP less 65.9 percent. Industry sources indicate that nationally, higher profit margins are obtained on generic prescription drug products. . . .

ANALYSIS

In recent months, there has been a significant increase in the number of SPAs proposed which would change the reimbursement methodology. State cost surveys have generally showed that state reimbursement could be reduced by a percentage greater than th~ proposed AWP discount level. The discount level has usually been reduced as the result of negotiations between the state and pharmacy representatives after the survey-results are known. In other cases, the state's legislature has responded to the escalating costs of Medicaid drugs by enacting legislation to increase the discount in the ingredient cost or decrease the dispensing fee. Legislation usually does not address the basis fur the ingredient cost reduction or the reasonableness of the dispensing tee, It is proving increasingly difficult to require states to provide statistical data to support their proposed payment rates. In addition, we believe that other sources of information and other factors can be used to evaluate the appropriateness of payment rates. As an alternative to requiring states to provide surveys or statistical data to support their proposed rates, we would ask states to compare their proposed rates to those of other states. For EACs, we would broaden our comparisons from surrounding states to all states because the market for drugs is national. In order to provide states with current payment rates of other states, we will maintain a list of each state's current EACs and dispensing fees on the CMS Web page. (For dispensing fees, we will put more weight on other states in the region, as these cost may differ by geographic cost differentials.) In short, we will look favorably on proposals to reduce reimbursement when there is a basis to conclude that the reduction will not affect pharmacy participation. Finally, we will approve rates set by the legislature or through negotiations, even if the rate differs from that suggested by other documentation, such as the rates of other states or from a state survey.

Because the regulations on dispensing fees are less specific (i.e., the standard is "reasonableness"), we would continue to allow States greater flexibility here. For instance, in addition to allowing states to reduce these fees to reflect lower costs, we would also

> permit states to increase or vary their rates in order to provide incentives to pharmacists to dispense less costly drugs, such as by allowing a higher dispensing fee for dispensing generic drugs.

(*Id*.)

83. OIG also issued reports in 1996 and 1997 to Delaware, District of Columbia, Nebraska, New Jersey, and North Carolina. With the exception of New Jersey, which reduced its reimbursement rate from AWP minus 2 to 8% to AWP minus 10% (less than the discount found by OIG), none of these five states changed their EAC formulas in response to OIG's report. In August of 1997, OIG issued a report to all states showing the result of their 11-state survey that the average discount off of AWP for generic drugs was 42.5%. (Ex. 130 (Abbott Ex. 158).) In that report, OIG also informed the states of the article published by Forbes on June 10, 1996 titled "Hooked on Drugs," which found that the true cost was 10 to 20 percent below AWP for brand name drugs and 60 to 85 percent below AWP for generic drugs. (*Id.*)

C. State Medicaid Programs Knew Drug Payment Methodologies Resulted in Payment of Marin or Profit on Ingredient Cost for Generic Drugs

84. Numerous state officials testified that they understood that their state payment methodologies for drugs resulted in the payment of a margin, or profit, on ingredient costs for generic drugs. For example:

(a) Jerry Dubberly, formerly the Pharmacy Director of Georgia Medicaid and currently the Chief of the Division of Medical Assistance, acknowledged that there was a profit margin in the ingredient cost formula, which, if eliminated, would require a higher dispensing fee to providers. (12/15/08 Dubberly Dep. at 314:3-315:2, Ex. 48.)

(b) Louisiana Medicaid's M.J. Terrebonne testified that Louisiana did not believe it was paying providers actual acquisition cost and intended to include profit in the ingredient cost. (3/31/2008 Terrebonne Dep. at 228:13-15, 270:14-271:6, Ex. 101.)

(c) Sandra Kramer spent twenty-one years as a policy analyst at Michigan Medicaid, researching payment methodologies and helping draft the state plan amendments dealing with drug payments to providers. (3/25/2008 Kramer Dep. at 31:20-36:18, Ex. 70.) She testified that the state Medicaid program paid providers margins beyond their acquisition costs on generic drugs. (*Id*. at 111:19-112:2; 176:22-177:4)

(d) Ed Vacarro formerly served as both the Chief Pharmaceutical Services Consultant and Assistant Director of Office of Utilization Management for New Jersey Medicaid. He testified that for the last two decades New Jersey was aware that it was paying providers greater than actual acquisition costs. (12/3/2008 Vaccaro Dep. 650:11-17, Ex. 116.)

(e) Rhode Island's Paula Avarista, Rhode Island Medicaid's Chief of Pharmacy, testified that Rhode Island intended to include a margin over the actual purchase price for pharmacy providers. (12/4/2008 Avarista Dep. at 130:1-131:3, Ex. 131.)

(f) Leo Sullivan, the former Director of Pharmacy Services for Tennessee Medicaid from 1989 to 2004, testified that there was no legal obligation to reimburse true provider acquisition cost. "I don't ever remember anybody ever telling me, Leo, you got a legal obligation to only pay true provider's cost." (3/12/2008 Sullivan Dep. at 217:16-219:17, Ex. 45.)

D. Medicaid Programs Use Spreads to Comply With The Federal Mandate To Maintain Equal Access to Pharmaceuticals And Services

85. A Medicaid "agency's payments [to pharmacies] must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population." (42 C.F.R. § 447.204 (2009).)

86. Accordingly, state Medicaid programs attempt to balance at least two competing goals when making policy decisions to set reimbursement rates: 1) achieve sufficient access to quality health care for the enrollees, and 2) administer the program within the budget constraints

imposed by the state legislature, in the context of negotiations with, or legal action by, pharmacist groups and efforts to comply with legislative mandates. (*See* 2/7/08 Robinson Dep. at 108:3-109:13, Ex. 132; 12/10/08 Bridges (Ark.) Dep. at 51:4-52:21; 226:4-14; 307:13-308:5, Ex. 41; 12/11/08 Bridges Dep. at 464:3-465:7, Ex. 96; 6/14/07 Jeffrey (Mass.) Dep. at 49:10-51:18, Ex. 53; 10/19/07 Jeffrey Dep. at 188:18-189:9, 190:22-191:11, Ex. 134; 11/24/08 Hautea-Wimpee (Wash.) Dep. at 99:9-100:7, 38:3-9, 40:20-41:5, 196:4-17, 202:4-10, 224:18-225:14, Ex. 43; 3/14/08 Wiberg (Minn.) Dep. at 50:10-18, 111:5-14, 136:7-22, 171:9-172:18, Ex. 103; 10/28/08 Farrand (N.H.) Dep. at 38:4-41:4, 121:2-122:3, 122:14-124:12; 12/10/08, Ex. 120; 3/19/08 Gorospe (Cali.) Dep. at 64:10-65:30, 145:3-146:17, Ex. 97; 12/15/04 Wells (Fla.) Dep. at 124:7-125:6, Ex. 69; 1/15/09 Gladden Dep. (Tex.) at 228:16-234:21, Ex. 136; 3/25/09 Gladden Dep. at 351:15-353:2, Ex. 137; 5/30/07 Gladden Dep. at 175:6-176:25, Ex. 138; 8/6/07 Dean (Tex.) Dep. at 186:9-187:2, 190:21-25, 224:4-15, Ex. 139; 8/19/08 Campana (Alaska) Dep. at 169:8-22, Ex. 95; 10/21/08 Weeks (N.C.) Dep. at 51:8-53:14, Ex. 54; 3/12/08 Sullivan (Tenn.) Dep. at 167:16-170:2, Ex. 45; 12/9/08 Denemark (Del.) Dep. at 150:17-153:17, Ex. 98; 12/15/08 Dubberly (Ga.) Dep. at 136:12-137:2, 138:8-140:2, 148:10-150:12, 257:3-21, Ex. 48.)

E. State Medicaid Programs Use Spreads to Cross-Subsidize Inadequate Dispensing Fees

87. Medicaid pharmacies dispensing fees are intended to cover the costs of dispensing. Dispensing costs consist of both overhead and labor. Overhead includes prescription related costs (*e.g.* department fees, delivery expense, computer expenses, containers and labels) and costs related to both prescription and non prescription sales (*e.g.* depreciation, real estate taxes, rent repairs, and utilities). Labor includes the total salaries, payroll taxes, and benefits paid to employees based on the time spent in the prescription department. (*See* December 2000 Myers and Stauffer Report, "A Survey of Dispensing Costs of Pharmaceuticals in the Commonwealth of

Kentucky," 8-14, Ex. 140; Hughes Expert Report at ¶ 46 ("Dispensing fee is intended to cover all of the pharmacy's cost, including the cost of storing, measuring, and delivering the prescription.") Ex. 51; 9/27/07 Reed Dep. at 572:9-15; 577:18-578:5, Ex. 141.)

88. During the relevant claims period (1994-2007), state Medicaid pharmacy dispensing fees have generally been in the range of $3.00-$5.00. (NCPA Pharmaceutical Benefits 2002, Ex. 142.)

89. Numerous studies have concluded that the average cost of dispensing exceeded the state Medicaid programs' dispensing fees. (Young Expert Report at 46, Ex. 34.) For example:

- In 2005, the Center for Pharmaeconomic Studies at the University of Texas at Austin found the average dispensing cost to be $9.62 (Ex. 143 at 2) (Tx. Ex. 1280);
- In 2007, Grant Thornton LLP undertook a nationwide study and found the average cost of dispensing to be $12.10 (Ex. 144, at 2) (Tx. Ex. 1281);
- In its 2007 Survey of Dispensing Costs of Pharmaceuticals in the State of Nevada, prepared by Myers and Stauffer in 2007, found that the average dispensing cost within the state to be $12.46 (Ex. 145 at 5) (2007 M&S Report for Nevada);
- In 2007, the University of Maryland School of Pharmacy determined that the average cost of dispensing per prescription was $11.71 (Ex. 146 at 5)(Abbott MD Ex. 32); Tetkoski Dep. at 201:7-15, (Ex. 37.)
- The Analysis of Pharmacy Dispensing Fees for the Indiana Medicaid Program, prepared by Myers and Stauffer, determined the average dispensing fee was $11.03 (Ex. 147 at 6) (2007 M&S Report for Indiana) and;
- The Survey of the Average Cost of Filling a Medicaid Prescription in the State of Louisiana, prepared by Myers and Stauffer, found the average dispensing cost to be $9.40 (Ex. 148 at 5) (2007 M&S Report for Louisiana).

90. The difference between the costs of dispensing and the dispensing fees has been generally in the range of $6.00-$7.00. (*See* ¶¶ 88-89, *supra*.) On average, the dollar difference between the AWP and the average price calculated by Duggan per prescription is about $3. (4/17/09 Duggan Ery Dep. 155:6-9, Ex. 149.)

91. Many states dispensing fees have remained unchanged for many years and failed even to keep pace with inflation. For example:

(a) New Jersey's dispensing fee, set at a $3.73 base rate, has been in place for over twenty years. (12/3/08 Vaccaro Dep. 12-2-08 at 93:20-94:1, Ex. 116);

(b) North Carolina has paid a $5.60 dispensing fee for generics since 1992 (Weeks Dep. at 68:2-69:1, Ex. 54.);

(c) Oklahoma's dispensing fee has remained at $4.15 since 1995 (Nesser Dep. at 171:17-173:6; 77:16-20, Ex. 77.);

(d) Delaware's dispensing fee, set at $3.65 on or before 1985, remained unchanged until 2003 (12/9/08 Denemark Dep. at 353:21-354:15, Ex. 98.);

(e) South Dakota's dispensing fee has remained at $4.75 since 1995 or before. (Iversen Dep. at 125:20-126:13, Ex. 150.);

(f) Wyoming's dispensing fee has remained unchanged at $5.00 for the last ten years. (Homar at 198:20 - 203:11, Ex. 36.);

(g) Maine's 30(b)(6) witness testified that the state's dispensing fee, set at $3.35, "hasn't increased forever." (Walsh Dep. at 74:21-75:11, Ex. 42.)

92. Current and former State Medicaid officials testified that they were aware that their states' allotted dispensing fees were lower than the actual costs of dispensing. *See, e.g.*

- Dep. of Edward Vaccaro (NJ) at 352:09-353:11, Ex. 116;
- Dep. of Cynthia Denemark (DE) at 179:17-181:15; 178:16-179:15, Ex. 98;
- Dep. of Allen Chapman (CO) at 136:17-137:8, Ex. 47;
- Dep. of Cody Wiberg (MN) at 172:3-18, Ex. 103;
- Dep. of Jerry Dubberly (GA) at 384:10-386:7; 332:5-334:6, Ex. 48;
- Dep. of Benny Ridout (NC) at 142:3-19, Ex. 76;

- Affidavit of Ron Gottrich, ¶ 5 (IL), Ex. 151;
- Dep. of Jerry Wells (FL) at 103:5-17, Ex. 69;
- Dep. of Susan McCann (MO) at 479:6-16, Ex. 152;
- Dep. of Leo Sullivan (TN) at 152:16-155:04, Ex. 45;
- Dep. of Joseph Fine (MD) at 107:2-108:13, Ex. 46;
- Dep. of James Kenyon (MI) at 19:11-20:14, Ex. 118.

93. In March 1993, the United States General Accounting Office prepared a Fact Sheet for Congressional Committees titled "Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland." (Ex. 153 (Abbott Ex. 458).) The Fact Sheet contained the following statements:

- "Although total Medicaid reimbursements exceeded the pharmacies' total drug purchase costs for the drugs we reviewed, whether this represents unreasonable benefits for the pharmacies is not clear. Neither HCFA nor the states have determined what would be an appropriate margin between reimbursements and costs. *Further, representatives of all nine pharmacies contended that because of insufficient dispensing fees they used the excess reimbursements to cover the drugs' dispensing costs.* (emphasis added)

- "HCFA and state Medicaid officials agreed that pharmacies must often use excess Medicaid reimbursements to cover their dispensing costs.

  "Because of the issues raised by pharmacy representatives and Medicaid officials about the sufficiency of dispensing fees and the lack of current data concerning such fees, we do not know the extent to which reimbursements in excess of drug purchase costs represent a potential source for Medicaid savings in the two states studied. This will remain unclear until new data are collected on pharmacies' actual dispensing costs. With this information, HCFA and the states could more realistically assess the potential to change reimbursement policies to achieve Medicaid savings. However, because of the 4-year moratorium on reducing reimbursement limits for outpatient prescription drugs and dispensing fees, HCFA headquarters and state Medicaid officials did not believe that surveys of dispensing costs or the evaluation of the appropriateness of state reimbursement policies would be appropriate at this time."

94. Numerous state officials testified that they understood that their state payment methodologies for drugs resulted in the payment of a margin on ingredient cost which was used to offset inadequacies in dispensing fees. (*See* 3/14/2008 Wiberg (Minn.) Dep. at 171:21-172:18, Ex. 103; 12/9/2008 Denemark (Del.) Dep at 179:17-181:15; 178:16-179:15, Ex. 98. (since at least 1994 Delaware Medicaid officials believed that dispensing fees were not adequate to cover providers' costs for dispensing drugs, but did not see this as a problem because margins available to providers on the ingredient cost portion of drug reimbursements). *See also*

(a) Georgia Medicaid's Jerry Dubberly testified:

> Q. (By Mr. Cole) Mr. Lavine asked you whether this practice of overcompensating on the ingredient cost and undercompensating on the dispensing cost was a secret practice, and you said, "No, not at all"; correct?
>
> A. Correct.
>
> Q. Georgia never did anything to conceal or hide this practice from CMS or HCFA; isn't that true?
>
> MR. LAVINE: Object to form.
>
> A. That is correct.
>
> Q. (By Mr. Cole) And it was -- you told me that it was a -- a -- it was common among all of the states, at least the states that you interacted with, that they also followed a similar practice; correct?
>
> MR. LAVINE: Object to form.
>
> A. That is correct.
>
> Q. (By Mr. Cole) And are you aware of any discussions among the state Medicaid programs to somehow conceal this practice from the federal Medicaid administrators at HCFA or CMS?
>
> MR. LAVINE: Object to form.
>
> A. No, I'm not.
>
> . . .

Q. (By Mr. Cole) Let me put it this way: Would it surprise you for HCFA or CMS to say that it had no idea that states, including Georgia, were following this practice throughout the mid to late '90s?

MR. LAVINE: Object to form.

A. I would be highly surprised by that statement.

(12/15/2008 Dubberly Dep. at 384:10-386:7, Ex. 48.)

* * *

When you joined the Georgia Medicaid program, is it your understanding that that practice existed prior to your joining Georgia Medicaid?

A. Yes.

MR. LAVINE: Let me object to form.

Q. (By Mr. Cole) Is it your understanding that that practice, like some of the other topics we've talked about today, was a practice employed by other state Medicaid programs?

MR. LAVINE: Object to form.

A. Yes.

Q. (By Mr. Cole) In other words, Georgia wasn't the only state that was overcompensating providers on ingredient costs at the same time that they were undercompensating providers for their dispensing costs; correct?

MR. LAVINE: Object to form.

MR. SULLIVAN: Object to form.

A. Correct.

Q. (By Mr. Cole) Would you say that -- that most of the states, if not all of the states that you communicated with or have communicated with, given your position as the Georgia State Medicaid director -- that the majority of those states have employed a similar practice?

MR. LAVINE: Object to form. And I'd request you clarify whether this is a question you're asking as an official opinion of

> the Georgia department or his personal opinion you're seeking now.
>
> MR. COLE: It's not a personal opinion. I'm asking -- I'm asking him as the representative of the Georgia Medicaid program if it's his understanding, based on the communications that he has had with other states, that those other states had a similar practice of overcompensating providers on the ingredient cost while they undercompensated providers for their dispensing costs.
>
> MR. SULLIVAN: Object to the form.
>
> A. Yes, that is my understanding.
>
> Q. (By Mr. Cole) Can you think of any state that did not have that practice?
>
> MR. LAVINE: Object to form.
>
> A. No.

(*Id*. at 332:5-334:6.)

(b) Cynthia Denemark, Pharmacy Consultant in Delaware, testified that by no later than 1994 Delaware Medicaid officials believed that dispensing fees were not adequate to cover providers' costs for dispensing drugs, but did not see this as a problem because margins available to providers on the ingredient cost portion of drug reimbursements. (12/9/2008 Denemark Dep. at 179:17-181:15; 178:16-179:15, Ex. 98.) She further testified that Delaware Medicaid officials expressed concern that adjustments to the ingredient cost portion without considering changes to dispensing fees would adversely impact providers, because providers rely on margins from ingredient cost to make up for inadequate dispensing fees. (*Id*. at 181:16-183:1; *see also* Ex. 154 (Dey Ex. 609).) Ms. Denemark testified:

> Q. Well, you indicated that the Delaware Medicaid Program wanted to increase the dispensing fee but because of budgetary reasons you were not able to do so; is that correct?
>
> A. That's correct.

> Q. Okay. So is it fair to say that because the Delaware Medicaid Program was unable to increase dispensing fees due to budgetary constraints that it was aware that providers relied upon a margin on the ingredient costs in some instances supplement for the inadequate dispensing fee?
>
> A. Yes.

(12/10/2008 Denemark Dep. at 363:19-364:9, Ex. 155.) Ms. Denemark further testified that the issue of cross-subsidization was discussed within the Medicaid director community since at least 1994. (*Id*. at 375:2-376:22.)

(c) North Carolina's Benny Ridout provide the following testimony:

> Q. Was it your experience in the '80s that efforts to reduce estimated acquisition cost would result in pressures to increase dispensing fees?
>
> MS. YAVELBERG: Objection, form.
>
> MS. HAYES: Objection, form.
>
> A. It was always the feeling, I think, of the pharmacy directors, those states that had a fee that was lower than what it cost to fill a prescription, that if they took anything off one side, they would have to put some on the other side to help so the pharmacists could make it. So if you got the actual acquisition cost on one side, and your fee didn't cover his cost to fill the prescription, you would have to raise that fee. In fact, I made that known to the OIG itself.

(12/5/08 Ridout Dep. at 142:3-19, Ex. 76.)

(d) Ron Gottrich, former Consultant Pharmacist with the Illinois Department of Public Aid, signed an affidavit that included the following statement:

> It was also commonly discussed amongst those who administered Illinois Medicaid's pharmacy benefit that Illinois Medicaid's reimbursement formula for ingredient cost provided a margin relative to the cost of the drug, and that this margin served to both offset the inadequacy of the dispensing fee and compensate for the fact that Illinois Medicaid did not reimburse drug claims in a timely manner.

(Affidavit of Ron Gottrich, ¶ 5, Ex. 151.) In June 2000, an internal Illinois memo discussed an impending reduction in ingredient cost reimbursement. It stated "we also expect arguments that dispensing fees should be increased to compensate for some of the revenue lost because of reductions to AWP." (IDPA Memo, AWP-IL-00016839, Ex. 156.)

(e) Jerry Wells, former Pharmacy Program Manager in Florida, testified that Florida Medicaid realized its dispensing fees were inadequate and that, as a result, pharmacies would "have to have some margin or markup on the ingredient cost of the drug to offset that." (8/15/2006 Wells Dep. at 103:5-17, Ex. 69.)

(f) Susan McCann, Pharmacist Consultant in Missouri, testified:

> Q. . . . But is it your belief and your understanding as the pharmacist working at Missouri Medicaid that Missouri Medicaid knew it was paying a higher ingredient cost reimbursement than acquisition cost in order to compensate for a dispensing fee that was lower than what it otherwise thought it should have been?
>
> (Objection)
>
> A. That was my understanding.

(11/7/2007 McCann Dep. at 479:6-16, Ex. 152.)

(g) In 2005, Louisiana increased its dispensing fee for 340B providers to $8.10, higher than the dispensing fee paid to non-340B providers. Louisiana's M. J. Terrebonne testified regarding the impetus for this change:

> Q. Do you recall if at some point Louisiana increased the dispensing fee paid to 340B hospitals?
>
> A. We did.
>
> Q. Do you recall the increase was roughly $8.10?
>
> A. Yes.
>
> Q. And that is considerably higher than the dispensing fee paid to providers in the Medicaid program, correct?

MR. FAUCI: Object to the form.

THE WITNESS: Yes.

BY MR. TORBORG

Q. Why was there a difference between the two dispensing fees?

A. The secretary of the department felt that because the 340B providers were getting paid at actual acquisition cost, that they should be reimbursed a higher dispensing fee.

(3/31/08 Terrebonne Dep. at 212:6-213:2, Ex. 101.)

(h) Joseph Fine, Manager and, later, Director of Maryland's pharmacy program testified that Maryland knew that it was underpaying on the dispensing fee side and had to use the ingredient cost payment to make up the difference. (2/09/08 Fine Dep. at 107:2-108:13, Ex. 46.)

(i) Frank Tetkoski, Manager of the Maryland Pharmacy Services Department, testified:

Q. And what's being talked about here is a possibility of having to adjust the fee upwards if you were going to cut the ingredient cost, right?

MS. YAVELBERG: Objection, form.

A. Right. Adjustments have to be made as more and more it evolved where the prescription was a part of the ingredient cost and the fee would need to be -- if you just unilaterally cut the ingredient cost it would be hard to put through as well as just a flat cut which as we discussed before it would be very hard to even put through.

Q. What the state officials said is you can't just look at one side of the equation and adjust it without looking it other side, right?

MS. YAVELBERG: Objection, form.

A. Well, you have to look at everything. Yes.

(12/11/2008 Tetkoski Dep. at 190:16-191:9, Ex. 37.)

* * *

Q. And then the next section, cost of dispensing survey, this is summarizing the survey that had been done by the University of Maryland School of Pharmacy, right?

A. Yeah. That's what it looks like. I didn't read this.

Q. And if you look at it it indicates that the average cost of dispensing per prescription is $11.71 with a median cost of $10.67, right?

A. That's what it's stating, yes.

Q. And then it end of this paragraph it states "Again, this does not mean that pharmacists are not receiving adequate payment. One needs to examine the profit levels that are obtained with the acquisition costs." Do you see that?

A. Yes.

Q. What does that mean?

MS. YAVELBERG: Objection, form.

A. They may be making some money on the acquisitions costs and that needed to be figured in.

Q. And that's not something that just kind of came out of the sky in 2007; this has been something that Maryland has been looking at every since you've been in the policy department, isn't it?

MS. YAVELBERG: Objection, form.

A. When we look at reimbursement, again, we look at everything. You've got to figure everything in.

Q. And that's something you've been doing since you started in the policy department in 1994, right?

MS. YAVELBERG: Objection, form.

A. I guess my answer is we look at everything. Are you saying that -- I'm not specifically what you're directing that at, but –

Q. You consider the whole picture, the dispensing fee adequacy and the ingredient cost payments.

A. Yes, especially if you're trying to make any kind of adjustments.

(*Id*. at 201:7-203:2)

(j) James Kenyon, pharmacy supervisor in Michigan, testified:

Q . . . I'd like to look at the second sentence of that paragraph as well as the third, which reads: "The process of setting EAC screens is closely linked and balanced with setting dispensing fees. Payers are able to have low dispensing fee rates if they have high EAC screens." Do you see that?

A. Yes.

Q. In your experience as a pharmacist and as working for Michigan Medicaid, do you have any reason to disagree with that statement?

MR. HENDERSON: Objection.

A. I would say I have no reason to, no.

* * *

Q. So, is it fair to say that if drug costs were high enough, that could offset a dispensing fee that was too low?

MR. HENDERSON: Objection.

A. I would say yes.

(3/25/08 Kenyon Dep. at 19:11-20:14, Ex. 118; *see also* Ex. 158 (Abbott Ex. 657) (1994 document produced by Michigan: "EAC focuses on establishing screens at the lowest price that will maintain pharmacy participation regardless of the cost of the drug dispensed. The process of setting EAC screens is closely linked and balanced with setting dispensing fees. Payors are able to have low dispensing fee rates if they have high EAC screens.")

(k) Lise Farrand, Pharmaceutical Services Specialist in New Hampshire, testified:

Q. And also similar to the last first we have a section regarding reasonable dispensing fee. And New Hampshire Medicaid determined that the $1.75 was a reasonable dispensing fee based upon what other third-party payors were paying, right?

A. That's what's listed in this document.

Q. It is not based on a study that was performed on dispensing costs, right?

A. That's not mentioned here.

Q. Rather, New Hampshire Medicaid was using a survey of the market of other third-party payors, right?

A. That is what's stated here.

Q. And the same is true for Estimated Acquisition Costs in that New Hampshire Medicaid reviewed what other third-party payors were applying as a discount to the AWP, right?

A. That's what's listed here.

Q. And it -- it states that -- well, that these discounts varied from 12 to 16 percent?

A. Yes.

Q. And so based upon what other third-party payors were doing, New Hampshire Medicaid determined that a 16 percent discount off of AWP was reasonable; is that right?

A. That is what is stated here.

Q. And it wasn't based on a survey of the acquisition costs of providers for purchasing drugs, right?

A. That's not mentioned here.

* * *

Q. And today the dispensing fee in New Hampshire Medicaid is $1.75, right?

A. Yes.

Q. And the dispensing fee was not set on dispensing costs but rather it was set based upon what other third-party payors were offering as their dispensing fees, right?

A. Yes.

. . .

Q. I'll withdraw. Let me rephrase. In considering its reimbursement methodology, New Hampshire considered both the dispensing fee portion and the EAC or ingredient portion, right?

A. Yes.

Q. And it determined that overall, the reimbursement was adequate to the providers, right?

MR. HENDERSON: Objection.

THE WITNESS: From reading those letters, yes.

(10/28/08 Farrand Dep. at 117:18-119:4, 165:17-166:22, Ex. 120.)

(l) Gary Cheloha, Pharmacy Consultant in Nebraska, testified:

Q. . . . And then if you go down towards the end of that second paragraph, it states: Changing the EAC calculation without considering what acquisition and operating costs currently are today, and then determining what is fair and reasonable for all, is inappropriate.

A. Yes.

Q. Sitting here today, as a 30(b)(6), do you agree that it is necessary to consider both the acquisition and operating costs, which is the dispensing and ingredient portion, prior to making any changes in reimbursement?

A. Yes.

Q. And then if you turn to the second page, it has a similar statement. It says at the very top: We are asking that the proposed change to the calculation of the appropriate discount for the EAC of drugs and the dispensing fee for each pharmacy continue to be fact-based and that neither be changed without consideration for the total reimbursement allowed to those pharmacies that choose to serve Medicaid clients. We request that HHS sponsor a new survey to determine the overall reimbursement and then implement its findings, as a number of other states have done. So once again, this sentence speaks to the need to consider both the discount of EAC and the dispensing fee?

A. Yes.

Q. And sitting here today, do you still believe that that's an important consideration to make?

A. Yes, I do.

(12/02/08 Cheloha Dep. at 186:3-187:14, Ex. 39.)

(m) New Jersey's Ed Vaccaro testified that "it's entirely permissible for States to use the estimated acquisition cost, the ingredient cost portion to compensate pharmacists for inadequate dispensing fees." (12/3/2008 Vaccaro Dep. at 352:09-353:11, Ex. 116.) Mr. Vaccaro also acknowledged that the state of New Jersey considered dispensing fees to be linked to ingredient costs such that "inevitably you would look at the two together."

Q. Okay. And given that this is a nationwide review comparing invoice price for drugs against AWP which -- do you agree that that is the ingredient cost portion of reimbursement?

A. Yes.

Q. Okay. Why would they discuss review of dispensing fees?

A: Dispensing fees are linked to ingredient costs.

Q. Can you elaborate further what you mean by link?

A. Well, the ingredient cost reflects the cost of purchasing a drug and a dispensing fee reflects the cost of dispensing that drug. Whether it's appropriate or not, it's what it is. It's a reflection of administrative costs for, or pharmacy costs, for dispensing the medication.

Q. Okay.

A. So inevitably you would look at the two together.

(*Id*. at 456:22-457:21.)

(n) Indiana's Marc Shirley testified:

Q. Do you think of those issues together as providing that total reimbursement must be adequate, or does reimbursement for each individual component need to be adequate?

> MS. ST. PETER-GRIFFITH: Object to the form.
>
> A. Once again, my sense on this is that ultimately your reimbursement for the service must be adequate to ensure participation by providers. And my sense is that providers probably don't much care one way or the other which side of the equation is which, as long as what they get from Medicaid is sufficient for them to render service.
>
> So I think, you know, we act administratively in light of that. It makes sense to have a total reimbursement that is sufficient to maintain provider participation.

(12/2/2008 Shirley Dep. at 145:5-22, Ex. 100.)

(o) On June 22, 2000, Minnesota's Cody Wiberg sent an e-mail to the National Medicaid Pharmacy Administrators wherein he stated:

> Some public and private third party payers have purposely kept the dispensing fee low precisely because there is a spread between AWP and AAC. In fact, when pharmacy organizations have sought an increase in dispensing fees, the AWP spread has been pointed out to legislators. It is true that ingredient reimbursement is supposed to be based on estimated acquisition cost. The ancillary costs of dispensing the drug are supposed to be accounted for by the dispensing fee. If the AWP spread disappears, the dispensing fee may have to be increased, especially for many of the 428 drugs currently in question. Many of these drugs require some type of compounding or other preparation.

(Ex. 159 (Abbott Ex. 492)

95. CMS's Deidre Duzor, currently the Director of the Pharmacy Division for Medicaid, testified that she "was aware . . . that there was a spread in the ingredient cost and in some states that may have led to states not keeping their dispensing fees up to date in terms of cost to dispense because the overall reimbursement was generous." (2/27/08 Duzor Dep. at 405, Ex. 160.) Duzor acknowledged a CMS letter indicating that "Some public and private third party payors have purposely kept dispensing fee low precisely because there is a spread between AWP and AAC." (*Id*. at 424-27; Ex. 161 (Abbott Ex. 493).) Duzor explained that after passage of the

Deficit Reduction Act, CMS acknowledged that states might need to review "their dispensing fees to assure that they are adequate to cover the cost of dispensing." (2/27/08 Duzor Dep. at 403-04, Ex. 160.) Duzor testified that CMS understood that ingredient costs and dispensing fees were connected and that a decrease in ingredient cost would require that dispensing fees increase. (*Id.* at 484:8-22.) Duzor further acknowledged that states paying very low dispensing fees would have to reassess their fees due to access concerns:

> Q. Is it fair to say you can think of states where you would not feel comfortable that paying a true acquisition cost with no other changes to the reimbursement system would not be sufficient to ensure access?
>
> * * *
>
> A. I don't know where the line would be drawn. But I think that there may be some states that were paying very low dispensing fees where that would not be adequate reimbursement for a pharmacy.
>
> Q. And would you feel comfortable assuming that a change to paying actual acquisition cost would not have resulted in any change to dispensing fees at any of the state Medicaid programs?
>
> * * *
>
> A. No. I think it may have resulted in a change in dispensing fees.

(*Id.* at 527-28.)

F. States Designed Payment Methodologies To Encourage Pharmacies to Dispense Generics

96. Numerous state officials testified that they understood that their state payment methodologies for drugs were designed to allow the payment of a margin on ingredient cost to encourage the dispensing of generic drugs, and documents uncovered during discovery support their understanding. For example:

(a) On March 18, 1992, the HHS DAB issued a decision, No. 1315, interpreting the "in the aggregate" provision of the 1987 Medicaid regulations. (Ex. 78 (Abbott Ex. 1153).) HHS DAB's Decision No. 1315 contained the following language:

> Section 447.333(b) of 42 C.F.R. provides in pertinent part that a state's drug payments may not exceed "in the aggregate" the specific limits established by HCFA for each drug plus a reasonable dispensing fee for each drug. Since the focus of the regulations is on a state's overall payment level, the State could reasonably have concluded that it could offset a lower than reasonable dispensing fee with ingredient costs which were higher than HCFA's specific limits as well as higher than the costs to the pharmacies themselves.
>
> The preamble to the 1987 regulations provides further support for the State's position. The preamble indicates that HCFA set an aggregate limit to give the states flexibility to adopt alternative methods of reimbursement. Contrary to HCFA's position, it is likely that HCFA intended a state to have flexibility in how it determined its overall payments and not merely with respect to the pricing of ingredient costs since HCFA recognized that some states paid pharmacies without separately identifying a dispensing fee.

(*Id.* at 8.)

HHS DAB's Decision No. 1315 also referenced an earlier ruling, which stated:

> The regulation can reasonably be read to permit states to pay more than an appropriately determined EAC for drug ingredient cost, but less than a reasonable dispensing fee, so long as the payments did not, in the aggregate, exceed the upper limit.

(*Id.* at 12.)

(b) An internal Illinois document from October 2001 that discussed an amendment to its reimbursement formula contained the following statement:

> The [OIG] audit reports that pharmacies can purchase generic and brand name drugs for 65% and 22%, respectively, less than the wholesale price. In this rulemaking, DPA is increasing the percentage deduction from the AWP for generic drugs from 12% to 20% and brand names from 10% to 11%. When deducted from the percentage discount allowed for generic and brand name drugs (64% [sic] and 22%), an overall profit of 44% is made by the

pharmacy when generic drugs are dispensed and 11% when brand name drugs are dispensed. *This profit disparity is another way this rule promotes the dispensing of generics over brand names*.

(Ex. 85 (AWP-IL-00008066).) (emphasis added)

(c) Tennessee's Leo Sullivan testified:

Q. And when you talk about an incentive you're talking about a financial incentive?

A. Yes.

Q. And what kind of financial incentive would you provide?

A. What, what I tried to make sure I did during this time, this -- I would say from '89 to '94, was, was make sure that there, there was profit to be made for a pharmacist for dispensing generic drugs. It -- these, these folks are pretty savvy. If I'm paying based on what I have submitted to HFCA at the time or CMS today on a state plan that says I will pay AWP minus 10 plus $4 or 3.91 or $4, whatever, for a brand name, and I'm setting MAC prices on the corresponding generic that pay the pharmacist his or her net cost, it's not going to take them very long to figure out which drug to process. When they can buy the drug at, you know, AWP minus 18, 20, 22, versus selling it at cost plus a dispensing fee, they're going, they're going to figure that out. And I'm shooting myself in the foot from a budget standpoint, from a, trying to be a responsible manager for the state's taxpayers. So you, you want to -- you want there to be some measure of profit, some incentive over and above a dispensing fee, to incentivize pharmacists to use the generic.

* * *

Q. From your experience, do you think it was well accepted amongst the Medicaid pharmacy administrative community that you would want to pay some profit on multiple-source drugs to incentivize their use?

MS. DAMOULAKIS: Objection.

A. It's just so fundamental, I don't remember discussing that with anybody. I think it's just -- it's something you -- you know, I mean it's just -- makes good sense. I don't, I don't remember any specific discussions with anybody on, you really need to make it profitable so that they will have an incentive to use it.

BY MR. TORBORG:

Q. In your view it's just one of those fundamental tenets of how you operate a state Medicaid pharmacy program.

A. One of my bosses long ago told me that the color of health care is green, and that's true.

(3/12/08 Sullivan Dep. at 60:7-61:14; 62:13-63:10, Ex. 45.)

(d) New Jersey's Mr. Vaccaro testified:

Q. So you testified, you know, just -- just before that there were greater margin percentages between AWP and actual acquisition costs for generics than there are for brands; correct?

A. Correct.

Q. And the AWP for brands tend to be higher than the AWP for generics; correct?

A: Correct.

Q. Okay. So by maintaining -- and I'm -- I'm asking whether this was a policy reason, whether it was a factual actual policy reason, but if you maintained the same reimbursement rates for both generics and brands, would you expect providers -- would that encourage providers to dispense more generics?

A. As it does today, yes.

(12/3/2008 Vaccaro Dep. at 493:3-21, Ex. 116.)

(e) When setting a MAC price, North Dakota Medicaid would consider the amount of profit pharmacists would make for a brand drug and try to include that amount of profit in the MAC price. Brendan Joyce, Administrator of Pharmacy Services, testified:

Q. Okay. I think you mentioned earlier that MAC -- the setting of MAC prices involved consideration of the gross margin that a pharmacy could earn on a brand product. Is that accurate?

A. Yes.

Q. Could you explain that a little further?

A. Well, let's say that a pharmacy earned on average, for the brand products where the AWP was not inflated, earned an average $12 per prescription.

Q. Okay.

A. Then we would try to do the same on the generic side as a whole.

Q. Okay.

A. To where if we could determine the actual acquisition cost of the product then we could determine how we could get them to make that average of what they had been making on the brand side.

(12/12/2008 Joyce Dep. at 106:16-107:13, Ex. 44.)

(f) Larry Iversen, South Dakota Medicaid's Pharmacy Director, testified:

Q. If you look at the second bullet point at the third sentence, it states, "The MAC price is then applied across all package sizes available, but is structured to insure that the profit to the pharmacist to dispense the generic product is higher than that associated with dispensing the brand product. This strategy provides pharmacists with an incentive to dispense generic products as well as to make recommendations to prescribers that they substitute brand products with generic therapy alternatives." As we established earlier, providing the provider with a profit was an important concern to South Dakota Medicaid, correct?

A. Yes.

(12/15/2008 Iversen Dep. at 99:15-100:8, Ex. 150.)

VI. NO FALSE OR FRAUDULENT CLAIM

97. The claim forms submitted by Medicaid providers contained information about the patient, the prescription including the NDC for which the claim is made, the amount of the drug dispensed, the prescribing doctor, the dispensing pharmacy and the pharmacies' usual and customary charge for that NDC. (*See* Ex. 164, Samples of Claim Forms.)

98. The claim forms submitted by State Medicaid programs to CMS requests the total amount of expenditures on prescription drugs. (*See* Ex. 165, CMS Form 64.) These forms did not contain any prices paid by the pharmacists or published prices.

Dated: November 2, 2009

Respectfully submitted,

/s/ Tara A. Fumerton
James R. Daly
Eric P. Berlin
Tara A. Fumerton
JONES DAY
77 West Wacker Drive, Suite 3500
Chicago, Illinois 60601
Telephone: (312) 782-3939
Facsimile: (312) 782-8585

Counsel for Defendant Abbott Laboratories Inc.

CERTIFICATE OF SERVICE

I, Tara A. Fumerton an attorney, hereby certify that I caused a true and correct copy of the foregoing Abbott Laboratories Inc.'s Rule 56.1 Statement of Additional Facts in Opposition To Ven-A-Care's Motion for Partial Summary Judgment to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 2nd day of November, 2009.

/s/ Tara A. Fumerton
Tara A. Fumerton